HELLENIC REPUBLIC **Athens: 10.06.2011**

MINISTRY OF HEALTH & SOCIAL SOLIDARITY

DIRECTORATE GENERAL OF HEALTH **Prot Nr: DYG3d/oik66084**

DIRECOTRATE OF MEDICNAL PRODUCTS AND PHARMACIES

DIVISION D

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MINISTERIAL DECISION

Subject: Provisions re pricing of medicines

Taking into consideration:

[…….]

we decide,

the following:

Article 1

1. Wholesale price of the medicinal products is the sale price to pharmacies. In the said price are included the gross profit margin of the wholesaler, which is calculated as percentage on the net price of manufacturer or importer as follows: a) for the prescribed medicines 5,4% and b) for OTCs 7,8%.

2. Retail Price of medicinal products is the sale price from the pharmacies to the patients and is determined on the basis of the wholesale price, increased by the legal profit of the pharmacy and the VAT.

   Highest Retail prices are the same throughout the country, with the exception of those areas where reduced VAT is applicable.

3. Net price of manufacturer or importer (ex-factory price)is the sale price from the importers, manufacturers, packagers to wholesalers. The net price is determined on the basis of the wholesale price reduced by: a) 5,12% for prescribed medicines and b) 7,24% for OTCs.

4. Maximum Hospital price for medicinal products is the sale price from the importers, manufacturers, packagers to the State, Public Hospitals, Social Care Units and the legal entities of public law of article 37 par. 1 of L. 3918/2011, the pharmacies of Private Clinics having more than 60 beds and to the pharmacies and the wholesalers of the medicinal products of article 12 par. 2 of L. 3816/2010.

Maximum hospital price is determined on the basis of the wholesale price reduced by 13%.

5. Especially for medicinal products of art. 12 par. 2 of L. 3816/2010, the retail sale price form private pharmacies is determined on the basis of the hospital price increased by 2,5% wholesalers' profit margin. On the resulting price 18% pharmacy's profit margin is added and on the final price the VAT is added. On these medicinal products the provisions on reductions do not apply.
6. The Social Insurance Price is the one resulting from the price of producer or importer reduced by 4%.
7. Medicinal products whose active ingredient is protected by a national or European patent are named "original" for abbreviation purposes. Originals are also considered the medicinal products manufactured by another enterprise following legal transfer of the relevant rights by the beneficiaries.
8. 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.
9. The designation of a medicinal product as original or as essentially similar shall be indicated on the legal marketing authorization.

Article 2

Profit Margins

1. For the wholesalers the gross profit margin is determined at 5,4% on the net price for prescribed medicines and at 7,8% for OTCs.
2. For pharmacies, the gross profit margin is 35% and it is calculated upon the wholesale price.
3. Especially for medicinal products of art. 12 par. 2 of L. 3816/2010, gross profit margin for wholesalers is 2,5% on the hospital price and on the resulting price 18% for the pharmacies.

Article 3

Discounts

Manufacturers, packagers and importers are allowed to grant additional discount only on the hospital price to the State, to public Hospitals, to Social Care Units of article 37 of L. 3918/2011, to IKA pharmacies and to the pharmacies of private Clinics having more than 60 beds, under the condition that it is mentioned on the sales invoice.

Article 4

Pricing of medicinal products – Medicinal Product Price Verification Sheet

1. The prices of medicinal products marketed legally in Greece are determined by Decisions of the Minister of Health, according to the provisions of this Decision, after the appropriate processing and recommendation by the Pricing Department of Medicinal Products of the Directorate for Medicinal Products and Pharmacies of the Secretariat-General for Public Health (GGDY) and on the basis of an opinion issued by the Pricing Committee.

2. The prices of medicinal products are determined following investigation of prices in the EU countries conducted by the competent Directorate for Medicinal Products and Pharmacies, Pricing Department of Medicinal Products, taking into account data from the pharmaceutical companies declared in the Price Verification Sheet.

3. The Medicinal Product Price and Data Verification Sheet is drawn up by the competent Pricing Department of Medicinal Products in electronic form and delivered to all the pharmaceutical companies. It is completed and signed by the marketing manager for each product and has the validity of a solemn declaration. The Sheet must always include: a) the states of the EU in which the medicinal product is marketed, b) the name (the same or different from the one used in Greece), the active ingredient, all the forms, packaging, strength levels and prices for each kind of product, the classification in accordance with the ATC, the National Organization for Medicines (EOF) code number, as well as the date the first national or European patent for the active ingredient of the product entered into force and expired. The Sheet is completed twice per year. The exact dates on which it must be submitted are set in a circular of the competent Directorate. Initially, when this Decision first enters into force, the Sheets must be completed and submitted to the competent Service by 14 June 2011.

4. The Service checks the accuracy of the data of the Sheet, cross-checking against the EOF register, as well as any other available source from the EU, the member states, the official organizations and networks.

5. Pharmaceutical companies concealing or for any reason not providing information or providing false or inaccurate information and data and thus ascertained, shall, following the issuing of an opinion by the Pricing Committee, be fined, by Decision of the Minister for Health, in accordance with the provisions of Article 13 of Law 3408/2005, by the competent Service.

6. Applications, Sheets, questions, data and any other communication by pharmaceutical companies with the Pricing Department of Medicinal Products, shall be addressed to farmaka.times@yyka.gov.gr.

Article 5

Pricing of medicinal products – Price investigation

1. In order to determine the prices of medicinal products, investigation is carried out by the competent Service in the member states of the EU where data exist and are published by the competent authorities and bodies of these countries. Access to the

data sources in question is possible through the special websites of the official sources of each EU member state. When access through the websites of the official bodies is not possible, or the data supplied are insufficient, the Service may also alternatively seek information from other sources (reliable price investigation organizations) and will on all occasions cite these sources. The investigation involves ascertaining each available price (ex factory, wholesale, retail, hospital, insurance, etc.).

2. Necessary data for the price determination of medicinal products are: a) the name of the product, b) its active ingredient, c) the strength of that ingredient, d) its pharmaceutical form, e) its packaging, f) its ATC classification, g) the marketing authorisation holder, h) the prices (wholesale and/or retail and/or hospital and/or ex factory), and the date of expiry of the first patent of the active ingredient. For the price determination it is necessary that the product has been given a price in the same form and strength in at least three member states of the EU. In respect of orphan medicinal products and blood derivatives, the Pricing Committee issues an opinion on the method of determining the price, if this is deemed necessary, and upon request by the Service.

3. The price of medicinal products–whether the product is still under patent or the patent has expired– is determined on the basis of the average of the three lowest corresponding prices of the product in the EU member states. In no circumstances may the prices of products whose patent has expired exceed 70% of the price of the same product when still under patent.

4. Using the data referred to in Article 4 para. 3 and Article 5 para. 2 of this Decision, the Pricing Department of Medicinal Products correlates the products, taking into account cumulatively the criteria of para. 2, where possible. Otherwise, extrapolation is used, and correlations with strengths and packaging, applying the provisions of Article 12 of this Decision. For correlations and comparisons with products from other EU countries, packaging which exceeds four times the size of the Greek packaging is not taken into account, except in the case of the products of Article 12 para. 2 of Law 3816/2010. The provisions of the previous sub-paragraph do not apply to the correlations and comparisons among products in cases where the packaging of the product, as approved and priced in EU member states, is unique and equal to or greater than four times the size of the corresponding Greek packaging.

5. To convert product prices from other currencies into Euro, the Pricing Department of Medicinal Products uses the official exchange rates issued by the Bank of Greece for the first working day of the two-month period preceding the issuance of the relevant Price Bulletin.

6. Orphan medicinal products are priced in accordance with the same provisions and using the same procedure described in this Decision.

Article 6

Pricing of medicinal products after expiry of the first patent

1. Wholesale prices of medicinal products, once the expiry of the first national or European patent for the active ingredient has been certified by all expedient means, are reduced by at least 30% by the Service, without any application from the marketing authorization holder. Marketing authorization holders may seek, by submitting an application, a lower price, without any limitation. When this Decision is first

implemented, and for the first six months following the reduction of the price, the provisions concerning price determination by price investigation, as described in the preceding article, do not apply.

2. Pharmaceutical companies are obliged to specify on the Medicinal Product Price Verification Sheet the date the first national or European patent of the active substance entered into force and expired. Otherwise, a fine is imposed by decision of the Minister for Health, in accordance with the provisions of Law 3557/2007.

Article 7

Medicinal products with similar active ingredient (essentially similar)

1. The wholesale prices of medicinal products with similar active ingredient and form are set at up to 63% of the wholesale price of the corresponding product during the last six months prior to the expiry of the first national or European patent. Marketing authorization holders may seek, by submitting the appropriate application, a lower price, without any limitation.

2. On first implementation of this Decision, within the first half of 2011, the prices of all essentially similar products are to be reviewed and re-determined. In order to ensure the smooth supply of hospitals with medicines of limited commercial interest, of low cost, old, tested and necessary for the public health, the transitional provision of Article 2 of Market Decree 8-2010 (on the maximum rate of reduction or increase in the prices of medicinal products) does not apply any further to those products whose retail price is 10 Euro and above, and which were granted marketing authorization after the year 2000. For the sake of equal treatment and upon request by interested parties there will be a case by case review of essentially similar products whose retail price is up to 15 Euro, and once the above 'ceiling' is lifted, the resulting price is lower than 10 Euro.

3. In the event that original product has a different packaging, extrapolation is done in accordance with the provisions of Article 12 of this Decision. A similar process of extrapolation is used where the price of the original product applies to another form or strength. In this case, the other cost factors are also examined.

4. If an essentially similar product is correlated to an original which is not marketed in Greece, the price is set on the basis of the provisions of Articles 5, 6 and 7 of this Decision.

5. In the case of parenteral solutions (sera) standard prices are set on the basis of the active ingredient, strength, packaging and other cost factors.

Article 8

Medicinal products produced in Greece

1. The price of the original medicinal products authorized and priced in the pharmaceutical market and not marketed in other EU countries, will be determined on the basis of cost elements. The said cost elements include production and packaging expenses for each form and package as well as Administration –

Distribution – Propagation expenses as determined in the corresponding lists updated every two years, calculated on the grounds of the average expenses of the sector.

2. 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) prices of active ingredients of any supplier, 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.

3. For those medicinal products for which research has been carried out for the active ingredient or the pharmaceutical form and there is a Greek patent and for which there are clinical pharmacokinetic studies and EOF marketing authorization, in order to determine the cost elements, the value of new investments, the research and development cost for the active ingredient or the pharmaceutical form as well as the assessment of expertise will be also taken into account.

4. 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 under license manufacturing. In any case and as long as the patent is in force the price of the medicine cannot exceed three times the average of the prices of medicinal products included in ATC 4 category, compared to the medicines of the same form and strength.

Article 9

Obligations of pharmaceutical companies

1. After the end of each administrative period, pharmaceutical companies are obliged to submit to the Directorate for Medicines and Pharmacies, Pricing Department of Medicinal Products, the following:

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

   1.2. Within four-months, the balance sheet and the statements of expenditures (in detail and aggregated).

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

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

   The competent Service, 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 medicinal sector. 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 Service. 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 10

Submission of Supporting documents and Deadlines for Price Determination

1. For the determination of the price of medicinal products for which a marketing authorization was issued by the National Organisation for Medicines (EOF) or the European Agency for Medicines (EMEA), or their price variation, an application must be filed. The above mentioned applications are submitted to the competent authority or they are sent in electronic form to the e-mail address farmaka.times@yyka.gov.gr within forty-five (45) calendar days at the latest from the date of issuance of each Price Bulletin at the website of the Ministry of Health.
2. 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.
3. In the case of an application for the determination of price of a new medicinal product, the competent Service shall issue an apposite 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 Service shall justify to the interested party the price set and the latter may submit to the Minister of Health 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 filed in the archives.
4. 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 90 days.

5. When, for specific reasons, the price of medicinal products must be frozen, the interested party may, in exceptional cases, request a deviation from freezing. The provisions of paragraphs 4 and 5 are also applicable in these cases. These specific cases of deviation from freezing concern a limited number of medicinal products resulting important losses to the company.

Article 11

General Provisions

1. Prices of medicinal products are determined 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, apart from the medicinal products which are determined by special provisions.
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 borne by pharmaceutical companies or by the importer. The same cost is borne 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 freezing, the Ministry of Health shall examine at least once a year if the macroeconomic conditions justify continuation of freezing without any change.
6. Packages of medicinal products destined for export shall not be controlled by a Market Decree.
7. 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.
8. In cases of Co-Marketing, the same price shall be determined. Should different prices arise, the lowest price is taken into consideration.

Article 12

Prices in case the producer or packager of the medicinal product changes or 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 hereof.

   With respect to the correlation of prices of medicinal products whose price was set in accordance with article 8 hereof, possible differentiation of the cost of packaging and production is taken into account.

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

   a) From the small to the large package unit and strength, price per unit 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

b) The unit price from the large to the small package 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

c) One dose injections, small sachets and ophthalmic solutions in a single dose, which are calculated proportionally, are exempted.

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 Social Solidarity, 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 and to submit their remarks on the resulting prices of the medicinal products within three (3) working days after the day following the session of the Pricing Committee. This period of time is extended by two (2) working days for the Price Bulletins that reevaluate and re-price the medicinal products. The remarks of the interested parties will be examined and taken into consideration in case a corrective Price Bulletin is eventually issued within twenty (20) days

Article 13

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 provisions.

The present shall be published in the Official Journal and enters into force on June 10, 2011.

THE MINISTER OF HEALTH

AND SOCIAL SOLIDARITY

ANDREAS LOVERDOS