**Ministerial Decision Nr. 57408**

Provisions on the pricing of medicinal products

**THE ALTERNATE MINISTER OF HEALTH**

Having considered…

**WE DECIDE AS FOLLOWS:**

**Article 1**
**Definitions**

1. "Maximum Wholesale Price of Medicines" is the price at which medicinal products are sold to pharmacies. This price shall include the wholesale gross profit margin, calculated as a percentage on the net price of producer or importer.

2. "Maximum Retail Price of Medicines" is the price at which medicinal products are sold by pharmacies to consumers, and it is defined by the wholesale price, adding the lawful profit margin of the pharmacy the applicable and VAT. Maximum retail prices shall be uniform across the country, excluding the regions where lower VAT rates apply.

3. "Net price of producer or importer (ex-factory)" is the price at which medicinal products are sold by importers, manufacturers or packers to wholesalers. The net price shall be determined on the basis of the wholesale price reduced: a) for prescribed medicines not reimbursed by social security agencies by 5.12%; and b) for medicines reimbursed by social security funds, 4.67%.

4. "Maximum Hospital Price of Medicines" is the price at which medicinal products are sold by importers, manufacturers or packers to the State, public hospitals, Social Care Units, EOPYY pharmacies of EOPYY and the legal entities of public law referred to in par. 1 of Article 37 of Law 3918/2011, pharmacies of private practices with over 60 beds and the relevant pharmacies and wholesalers for the medicinal products of par. 2 of Article 12 of Law 3816/2010. The maximum hospital price shall be determined on the basis of the wholesale price reduced by 13%.

5. In particular for medicinal products within the scope of par. 2 of Article 12 of Law 3816/2010, a special method for the calculation and determination of the wholesale and retail prices shall apply as follows: a) a wholesale profit margin of 2% shall be added to the hospital price in order to obtain the Special Wholesale Price. On the resulting price, a fixed amount of €30.0 shall be added as profit margin of the private pharmacy to obtain the retail price. The VAT shall be added to the final price.

6. "Reference medicinal product" shall mean a medicinal product which has been authorised under Article 6 of Joint Ministerial Decision *ΔΥΓ3α/οικ*.82161/24.8.2012 (Government Gazette 2374/b/24.8.2012) in accordance with the provisions of Article 8 thereof.

7. "Generic medicine" shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference

medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form.

8. The status of a medicinal product as a reference or generic product shall be indicated in its marketing authorisation.

**Article 2**
**Profit margins**

1. For wholesalers, gross profit margins shall be determined as follows:
a) for non-prescribed medicines (OTC), at 7.8% on the ex-factory price;
b) for prescribed medicinal products not reimbursed by social security agencies, at 5.4% on the ex-factory price;
c) for medicinal products reimbursed by social security agencies, at 4.9% on the ex-factory price; and
d) for the medicinal products of par. 2 of Article 12 of Law 3816/2010, at 2% on the hospital price. The resulting price shall hereinafter be referred to as "special wholesale price".

2. For pharmacies, gross profit margins shall be determined as follows:
a) for non-prescribed medicines (OTC), at 35% on the wholesale price;
b) for prescription medicinal products not reimbursed by social security agencies, at 35% on the wholesale price;
c) for medicinal products reimbursed by social security agencies and having a wholesale price of up to €200, at 32,4% on the wholesale price;
d) for reimbursed medicinal products having a wholesale price or a special wholesale price over €200, the profit margin of private pharmacies shall be equal to a fixed amount of €30.00.
e) for reimbursed medicinal products included in the list of par. 2 of Article 12 of Law 3816/2010 and having a Special Wholesale Price of up to €200, the profit margin of private pharmacies shall be determined at 16% on the Special Wholesale Price.

**Article 3**
**Discounts - Credit**

1. Manufacturers, packers and importers may, without any quantitative restrictions, offer additional discounts, on the hospital price, exclusively to the State, public hospitals, the Social Care Units of Article 37 of Law 3918/2011 and the pharmacies of EOPYY, provided that any such discount is indicated in the sale invoice.

2. Manufacturers, packers and importers may, without any quantitative restrictions, offer a discount on the wholesale price for the non-prescribed (OTC) medicines, as well as for the medicines referred to in par. 2 of Article 12 of Law 3816/2010. For all other products, manufacturers, packers and importers may offer a discount of up to 5% to wholesalers, pharmacies and cooperatives, provided that the amount of the discount is indicated in the sale invoice.

3. Manufacturers, packers and importers are obliged to supply their products to pharmacies, wholesalers and cooperatives on credit, provided that such arrangement is indicated in the sale invoice. The credit shall be for a period of not less than two months.

4. The possibility of the same percentages of discounts and period of credit shall also apply to sales by wholesalers to pharmacies, provided that such arrangement is indicated in the sale invoice.

5. For the pharmacies of private practices with over 60 beds, the additional discount under paragraph 1 shall be applied on the hospital price. As a requirement, such additional discount shall be indicated on the sale invoice.

6. Where a violation of the discount limit or non-compliance with the requirements of paragraph 2 of the present article is noted, on the basis of the sale invoices submitted to EOF, the relevant companies shall incur, further to the sanctions provided for in the Market Control Code, an immediate reduction of the price of the medicinal product concerned in an amount proportionate to the additional discount offered.

**Article 4**
**Pricing of reference medicinal products**

1. Before pricing a reference medicinal product, the competent Service of EOF shall undertake a survey in EU Member States in which data exists and is announced by the competent authorities, at the agencies of these countries or at official and reliable European institutions. Access to such data sources shall be ensured through dedicated websites of the official sources in each Member State of the EU and/or official and reliable agencies such as EURIPID and OBIG, and the relevant service of EOF shall each time disclose such sources. Price research shall encompass any available price (ex-factory, wholesale, retail, hospital, insurance, etc.). Retail or wholesale prices shall be converted to ex-factory prices using a methodology and rates as announced from time to time by the competent service of EOF, as well as any other relevant information and data used in the pricing.

2. The following information shall be deemed essential for pricing: a) name of medicinal product; b) active substance; c) strength in active substance; d) pharmaceutical form; e) pack size; f) ATC classification; g) the person responsible for the marketing; 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. For the price determination, the product must have been priced and be marketed in at least three EU Member States.

3. The prices of medicinal products under protection of the first patent of the active substance, result from the average of the three lowest prices of the respective products in EU Member States.

4. Data reported by pharmaceutical companies via Price Verification Sheets may additionally be taken into consideration. Any sale invoices shall not be considered as valid supporting documents in this respect. An electronic template of the Price Verification Sheet shall be prepared by the competent services and forwarded to all pharmaceutical companies. It shall be filled in and signed by the person responsible

for the marketing of each medicinal product and shall be deemed a legally binding solemn declaration under Law 1599/86. The Price Verification Sheet 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 EOF code, 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 filled in twice a year; the exact dates shall be specified by the relevant Service of EOF. Price Verification Sheets, submitted exclusively to the competent department, may be forwarded by the competent service or by companies to HDIKA for further processing, which operates the relevant software to that end. Following the opinion of the Pricing Committee, prices may not be issued for those medicines, for which the above data has not been submitted.

5. The competent department shall verify the accuracy of the data contained in the Sheet by cross-checking with the Register of EOF; the latter shall maintain and update such Register, obtaining any relevant information from any available official source, as well as any other sources of the member states of the European Union, official or reliable agencies and networks.

6. Any companies which withhold information or for any reason whatsoever fail to report or are found to have reported inaccurate or false data, and this is certified, 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 as well as any other sanctions provided for by applicable laws.

7. The filing 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 via the e-mail address price_list@eof.gr.

8. No prices shall be issued for medicinal products which, although authorised, have not recorded sales for the past three years before the issuance of the list or for three consecutive years following the issue of their marketing authorisation, irrespective of any withdrawal of authorisation by a decision of EOF. For these products, a supplementary price bulletin may be issued following an application by the companies concerned.

9. By an application submitted to the competent service, the marketing authorisation holder may request a lower price, without any restriction; such lower price shall be approved immediately through a supplementary/corrective Price Bulletin.

**Article 5**

**Pricing of reference medicinal products after the expiry of the first Patent protecting the Active Substance**

(previous paragraph 1 deleted)

1. Pharmaceutical companies must indicate in the Price Verification Sheet, data on the medicinal product concerned, and more specifically the full EOF-assigned code, the

start and expiry date of the first National or European patent protecting the active substance of the medicine, as well as the requested price. Otherwise, a fine shall be imposed by decision of the Minister of Health in accordance with the provisions of Law 3557/2007 and Article 69 of Law 3984/2011. Following the opinion of the Pricing Committee, any products that fail to comply with the aforementioned information requirement may be excluded from pricing.

2. (text missing) For the medicinal products whose patent protection expired but no generic products are marketed, EOF may suggest, following the consent of the Pricing Committee, that the price of the medicine will result from the average of the three lowest respective prices of the said medicinal product in the EU Member-States, in which official data exists and is announced.

3. Ceilings on price reductions may be imposed, following a recommendation of EOF and with the concurrent opinion of the Pricing Committee, for low-cost or other special cases of medicinal products, with a view to protecting and keeping them in the market.

4. Upon application filed to the competent service, the marketing authorisation holder may request a lower price, without any restriction; such lower price shall be approved immediately through a supplementary/corrective Price Bulletin.

**Article 6**
**Generic medicinal products**

1. The price of medicinal products with the same active substance and pharmacotechnical form that enter the market after the expiry of the validity of the first National or European Patent of the active substance of the reference medicinal product, is determined at a reduced level, at least by sixty per cent (60%) in relation to the retail price of the respective reference medicinal product, exactly before the expiry of the validity of the first National or European Patent of the active substance.

2. Generic products may not obtain a price exceeding 80% of the price obtained by the reference medicinal products after the end of their patent protection.

3. In case the reference medicinal product has a different pack size or strength, 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 original product is priced in a different form or strength. In this case, the other cost parameters shall also be considered. When a generic medicinal product corresponds to a reference product not marketed in Greece, its price shall be determined in accordance with the provisions of Articles 5, 6 and 7 hereof, following a recommendation from the competent department and the opinion of the Pricing Committee.

4. For parenteral preparations (serums), uniform prices shall be determined on the basis of the active substance, strength, pack size and other cost parameters.

5. Upon application filed to the competent service, the marketing authorisation holder may request a lower price, without any restriction; such lower price shall be approved immediately through a supplementary/corrective Price Bulletin.

## Article 7
## Medicinal products manufactured in Greece

1. For medicinal products authorised and priced in the domestic pharmaceutical market and not marketed in any other EU country, their 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 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 elements: a) default interest; 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 research laboratory; e) third-party fees and other costs not related to the production or marketing of medicinal products.

3. In 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).

## Article 8
## Procedural issues for pricing

1. On the basis of the data set out in Article 4, the competent service of EOF shall assign prices to medicinal products taking into account, cumulatively, the criteria of par. 2 and 3, where possible.

2. For converting any prices of medicinal products denominated in other currencies into Euro, the Department of Medicines Prices shall use the official exchange rates published by the Bank of Greece on the first business day of the calendar two-month period prior to the issuance of the relevant Price Bulletin.

3. In exceptional and strictly limited cases, special pricing criteria may be introduced following a reasoned and well-founded recommendation from the competent service of EOF and with the concurrent opinion of the Pricing Committee.

4. The Price Bulletins shall be attached to the relevant Ministerial Decision for the issue thereof and shall be posted at the website of the Ministry of Health, following a recommendation from the competent department and review of the prices and opinion of the Pricing Committee. Prices may be updated up to four times a year. At the first implementation of this Decision, increases shall only be possible following a reasoned and well-founded opinion of the Pricing Committee and upon request of the marketing authorisation holder; any decision on such request shall be included in the supplementary/corrective Price Bulletin.

## Article 9
## Obligations of pharmaceutical companies

1. After the end of each management period, pharmaceutical companies shall be required to file to the Directorate of Medicines and Pharmacies and the Directorate of Medicines Prices, the following data:

1.1. Within a period of one month, volume and value data on their sales during the management period under review;

1.2. Within a period of four months, the 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 records. The competent Service, if it deems it necessary, may use data from related companies and any other available data.

3. Companies producing or importing other goods apart from medicinal products, shall keep separate accounts for their 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 industries 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 authorised by the competent service. Companies which, under the Code on Tax Books and Records 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.

5. Pharmaceutical industries, 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 Article 30 of Legislative Decree 136/1946 (on the Market Control Code).

6. Pharmaceutical companies shall ensure the availability of stocks of their products equal to three (3) months' supply per product code, based on the sales of the previous year.

## Article 10
## Submission of supporting documents and deadlines for pricing

1. For the purpose of determining the prices of medicinal products for which a marketing authorisation has been granted by EOF or by the European Medicines Agency (EMEA), change of their price may be requested, for which the relevant application shall be required. Applications shall be submitted at the competent Service or emailed to price_list@eof.gr.

2. For all medicinal products of foreign origin (manufactured, packed, imported abroad), 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 data supporting the application is inadequate, then the above deadline commences from the date the applicant will file all data provided for. 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 against the decision. 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 event of an exceptional number of applications or in exceptional circumstances, the period may be extended for a number of days. 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. A marketing authorisation holder may request the deletion of his 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 5 and 6 hereof shall be taken into account.

6. For the determination of the price of medicines for which an authorisation for parallel import has been granted by EOF, or for the change of their price, a relevant application shall be required. Such applications shall be filed to the competent service or emailed to: price_list@eof.gr. Furthermore, a Solemn Declaration under Law 1599/86 shall be submitted, stating the price of purchase from the supplier with an official sale invoice for the imported quantity attached thereto.

## 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. For the OTC medicinal products, the indicated retail price is suggestive and constitutes the maximum 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 Euros in value.

5. In the event of a price freeze of medicinal products or of certain categories of medicinal products imposed by the competent authorities of the Member State, a review shall be carried out, at least one a year, to ascertain whether the macroeconomic conditions justify that the freeze be continued unchanged.

6. In exceptional cases, the marketing authorisation holder can ask for a deviation of the price freeze, if there are special reasons justifying it. The application must include adequate description of these reasons. The member states ensure a justified decision is taken for every such application and that it is notified to the applicant within 90 days.

7.
Manufacturers, packers and importers of medicinal products shall be required to withhold a levy in favour of the Hellenic Association of Pharmacists (0.4‰ of the wholesale price) for their sales to pharmacies. The levy shall be collected and transferred to the Hellenic Association of Pharmacists 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/invoicing parties. The necessary supporting documents for the reimbursement of the resources are specialised by the resolution of the Board of Directors of the Hellenic Association of Pharmacists and will be the same with those filed to the Tax Authorities for the return of the exports VAT, based on the law in force from time to time. The requests for the reimbursement of the resource with the necessary supporting documents from the wholesalers will be filed to the Hellenic Association of Pharmacists not later than the end of the 5$^{th}$ month from the end of the six-months period to which they relate. More specifically, for the exports effected within the first six-months period of each year, the requests will be filed not later than November 30 of the current year, and for the exports effected within the second six-months period of the current year, the request will be filed not later than May 31 of the next year. In order for the timely nature of the requests to be decided, for the purposes of reimbursing the 0.4%, the date recorded on the shipping documents will be taken into account as the starting point, which (shipping

documents) prove the dispatch of the medicinal products from one state to the other. Clearance and reimbursement of the withheld contributions will be effected within six (6) months from the date the request and the supporting documents were lawfully filed.

8. In the case of co-marketing 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 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. As regards 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:

| Increase in pack size (%) | Reduction of proportional 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%:

| Reduction in pack size | Increase of proportional 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 and over | 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 prices as determined by the procedure specified herein shall be published in the Pharmaceutical Price Bulletin, following an opinion from the Pharmaceutical Pricing Committee. The Price Bulletins shall be attached to the Ministerial Decision establishing the Price Bulletin and shall be posted on the website of the Ministry of Health.

6. Interested parties may, within three (3) business days of the date after the meeting of the Pricing 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.

7. Where deemed necessary by the relevant first- or second-degree (review) Committee, certain packs, forms or strengths of a medicinal product may, following a reasoned decision, be excluded from the positive list of reimbursed medicines.

**Article 13**
**Authenticity sticker or barcode of medicinal products**

The requirement to indicate the necessary data on the authenticity sticker 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 *ΔΥΓ3(α)/οικ.*7789/22-01-2013 (Gov. Gazette B' 94), is hereby repealed.

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

Athens, June 14, 2013

THE ALTERNATE MINISTER OF HEALTH
**MARIOS SALMAS**