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Athens, 14 - 01 - 2014
Protocol No. οικ.

Subject: "Pricing of Medicinal Products and Other Provisions".

MINISTERIAL DECISION

THE MINISTER OF HEALTH

Having considered:

1. The provisions of article 14, par. 3 of Law 3840/2010 (Gov. Gazette A' 53).
2. The provisions of article 90 of the P.D. 63/2005 "Codification of legislation for the Government and Government bodies" (A΄ 98).
3. The P.D. 119/013 "appointment of the Vice-President of the Government, Ministers, Alternate Ministers and Deputy Ministers" (Gov. Gazette A 153).
4. The provisions of the L.D. 96/1973 and mainly article 17 as amended and in force (Gov. Gazette A 172).
5. The provisions of the L.D. 136/1946 "for the Market Police Code" (Gov. Gazette A' 298), as amended and in force.
6. The provisions of article 13 of Law 3408/2005, as amended and in force (Gov. Gazette A 272).
7. The provisions of Law 3842/2010 (Gov. Gazette A 58) as amended and in force.
8. The provisions of article 4 par. 2 of Law 3899/2010 ((Gov. Gazette A 212), for the amendment of VAT Code.
9. The provisions of article 32 of Law 1316/1983 "Establishment, Organisation and competencies of EOF" (Gov. Gazette A 3), as already amended and in force.
10. The provisions of the P.D. 95/2000 "Organisation of the Ministry of Health and Welfare" (A΄ 76), as amended and in force.
11. The provisions of articles 38, 39, 40 and 51 of Law 3918/2011 (Gov. Gazette A 31) as amended and in force.
12. The provisions of articles 19, 20, 21 and 23 of Law 3052/2012 (Gov. Gazette A 41).

13. The Joint Ministerial Decision (KYA) No ΔΥΓ3α/Γ.Π.32221/2013 (Gov. Gazette 1049/B/29.4.2013), "approximation of Greek legislation to the respective European one in the area of production and marketing of medicinal products for human use, in compliance with the directive 2001/83/EC "on the Community code relating to medicinal products for human use (Law 311/28.11.2001) as in force and as amended by the Directive 2010/84/EU, regarding pharmacovigilance (Law 348/21.12.2010) regarding pharmacovigilance.
14. The Ministerial Decision No ΔΥΓ3(α)/οικ.86767/10.9.2012 "Revocation of the decision for the application of competencies to EOF regarding the pricing of medicinal products" (Gov. Gazette B 2462).
15. The Ministerial Decision No ΔΥΓ3(α)/οικ.94274/28.9.2012 "Application of article 15 in Law 4052/2012" (Gov. Gazette B 2675).
16. The Decision of the Alternate Minister of Health No ΔΥΓ3(α)/οικ.7789/22-01-2013 (Gov. Gazette B' 94).
17. The Decision of the Alternate Minister of Health No 57408/14-06-2013 (Gov. Gazette B' 1446) "Provisions for Pricing of Medicinal Products".
18. The Ministerial Decision No 69010 (Gov. Gazette 1814/25-07-2013) "Provisions for Pricing of Medicinal Products".
19. The provisions of the Ministerial Decision No ΓΠ/οικ/90281 (Gov. Gazette 2467/B/02-10-13) "Approval of the positive list set out in article 12(a) of Law 3816/2010", as amended and in force.
20. The provisions of article 12 of law 3816/2010 (A΄6), as supplemented by par. 5 of article 63 of Law 3918/2011 (A΄31) and the provisions of article 51 of law 3918/2011 (A΄31).
21. The Ministerial Decision No Γ.Υ./ΟΙΚ 6161 (Gov. Gazette 2761/B/30-10-2013).
22. The fact that no expenditure is incurred against the State Budget from this decision, we decide:

That the Ministerial Decision No 113429 (Gov. Gazette 3117/B/09-12-2013) is substituted by the following:

WE DECIDE

Article 1:
Definitions of Priced Medicinal Products

1. Reference medicinal product is a medicinal product which is approved by virtue of article 11, par. 2(a) of the Joint Ministerial Decision (KYA) No ΔΥΓ3α/Γ.Π.32221/2013 (Gov. Gazette 1049/B/29.4.2013), according to the provisions of article 9 thereof. Exclusively and only for pricing purposes, a medicinal product is no longer protected (off-patent) after the documentation that the protection period of its active substance has expired, either in Greece or in other countries of the EU. In case no reliable data exist, in relation to the expiration of the patent of the active substance, as an alternative, the expiration of the ten-year or possible eleven-year patent period provided for by article 11, par. 1 of the Joint Ministerial Decision No ΔΥΓ3α/Γ.Π.32221/2013 (Gov. Gazette B 1049) applies, and respectively the six-year protection period for the medicinal products that obtained a marketing authorisation before the Joint Ministerial Decision No ΔΥΓ3α/83657/2006 (Gov. Gazette B 59/24.1.2006) entered into force. The on-patent period for the active substance supersedes the protection period if the former ends at a posterior time.

Generic is a medicinal product, as defined in article 11, par. 2(b) of the above Joint Ministerial Decision, with the same quantitative and qualitative composition in terms of active substances, the same pharmaco-technical form with the reference medicinal product whose bioequivalence with the reference medicinal product has been proven, based on the appropriate bioavailability studies. Various salts, esters, ethers, isomers, isomer mixtures, complexes or derivatives of an active substance are considered to be one and the same substance, unless their properties differ substantially, in terms of safety and/or efficacy. Various pharmaco-technical forms administered Per Os with direct release are deemed as the same pharmaco-technical form. The characterisation of a medicinal product as a reference medicinal product, as under or no protection, or as generic is made by EOF.

Article 2:
Prices of Medicinal Products

1. The maximum producer's or importer's price (ex-factory) is the sale price from the marketing authorisation holders (MAHs) and the importers, manufacturers, packagers and distributors deemed equal therewith, to the wholesalers and is calculated in accordance with the provisions hereof. The producer's price is based on the wholesale price reduced (a) for prescribed medicines which are not reimbursed by the Social Insurance Agencies by 5/12% and (b) for those whose cost is reimbursed by the Social Insurance Agencies by 4.67%.

2. Maximum Wholesale Price of Medicinal Products is the price at which medicinal products are sold to pharmacies. This price includes the gross profit margin of the holder of the license for the wholesale of medicinal products, which is calculated as a percentage on the maximum price of the Marketing Authorisation Holder.

3. Maximum Retail Price of Medicinal Products 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 and the applicable VAT.

4. Maximum Hospital Price of Medicinal Products is the price at which medicinal products are sold by the Marketing Authorisation Holders to the State, public hospitals, Social Care Units, EOPYY pharmacies of EOPYY and the public law legal entities referred to in par. 1 of Article 37 of Law 3918/2011, pharmacies of private clinics with over 60 beds and the relevant pharmacies and wholesale drugstores 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 maximum producer's price, with the exception of the first application hereof, where the maximum hospital price is determined based on the maximum wholesale price reduced by 13%.

5. Especially 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. For the needs of pricing, the provisions for pricing of generics also includes the case of par. 3 of article 11 of the Joint Ministerial Decision (KYA) No ΔΥΓ3α/Γ.Π.32221/2013 (Gov. Gazette 1049/B/29.4.2013), as well as the cases of article 12. For the case of the pricing of medicinal products, which obtain license by virtue of article 14 of the above KYA, the "reference product" preserves its price until the end of the 10-year data protection period and the second (and any subsequent product) is priced in accordance with the "reference product" within the period before the expiration of the 10-year data protection period of the (initial) "reference product".

7. The manner the above maximum producer's prices are calculated for each category of medicinal product separately and thereafter, the margins and the manner the other prices set out in the preceding paragraph are calculated, is defined in detail by virtue of the Ministerial Decision of the Minister of Health, before the publication of occasional Prices Bulletin, which acts as a market police regulation.

8. The MAHs may request reductions from the maximum ex-factory prices which are immediately accepted with a supplementary prices bulletin. The MAH is entitled to file an application for the deletion of a medicinal product from the Prices Bulletin, if the termination of the marketing thereof has been previously approved. The voluntary reduction of the price of a reference medicinal product does not reduce the price of the respective generic, save and only in the case the MAH of the generic requests so with the relevant application thereof.

Article 3:
Profit margins

1. For wholesalers, gross profit margins shall be determined as follows: a) for non-prescribed medicinal products (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 medicinal products (OTC), at 35% on the wholesale price; b) for prescribed 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 4:
Discounts and Credit

1. Manufacturers, packers and importers may, without any quantitative restrictions, offer additional discounts, on the hospital price, 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) medicinal products, as well as for the medicinal products 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 10% 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 granted 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 clinics 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 or will be concluded by a written agreement between the two parties.

6. The discovery of the transgression of the discount limit or of the non-compliance with the requirements of paragraph 2 of this article 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 5:
Procedural and administrative issues

1. The maximum price of all categories of medicinal products is calculated by the competent service of EOF, as described in the provisions of this Ministerial Decision and the relevant laws and is filed to the Directorate of Medicinal Products and Pharmacies of the Ministry of Health in order for its lawfulness to be examined and for approval. All sources of data, dates, assumptions, conversion factors and exchange rates, as well as any relevant information applied to the calculation of prices are each time posted at EOF's website. The prices bulletins are attached to the Ministerial Decision following the evaluation and granting of opinion by the Medicinal Products Prices Committee and the consent of the competent service. The Ministerial Decision illustrates all relevant prices, while the website of the Ministry of Health depicts only the ex-factory, the wholesale and the retail sale price of the medicinal products.

2. According to the law, the prices of all medicinal products are revised twice per year and the prices bulletins are issued, in January and July respectively, of each year. Additional prices bulletins may be issued once the above dates elapse for the pricing of new medicinal products. For the purposes of smooth organising and operation of the market and for the continuous access of patients, a prices bulletin of new medicinal products which has been duly prepared by EOF at an preceding time, may be issued in parallel with the general prices bulletin, although the producer's prices and the exchange rates have been calculated at a later stage. Before their filing to the Minister of Health, EOF sends the concluded, based on the data available to it, prices, to each MAH separately for any comments. Any remarks are filed within three (3) business days to EOF, who, after examining them, makes its final suggestion to the Minister of Health and publishes it.

3. Objections are all answered by the competent department in writing, with the proper justification and documentation. At any time, MAHs may request further reductions of the prices by the competent service of the Ministry of Health, which (reductions) may later be automatically applied without the need for EOF or the Pricing Committee to grant their opinion.

4. No increases are permitted at any price revision. The new prices may be equal or less than the applicable ones. Increases are accepted only in case of error corrections. Once the marketing authorisation is obtained and the application is filed, the new medicines are priced within the time limits defined in the Transparency Directive, as transposed into National Law. In the case of generics, prices are published within 30 days from the application of the MAH. Prices are not issued for medicinal products that did not show any sales during the past three years, before the issue or revision of prices. For these medicinal products, prices are issued upon the application of the marketing authorisation holder, which are included in the first Prices Bulletin issued after the application, only if they have been exempted from the revocation of their marketing authorisation, in accordance with article 40, par. 6 of the ΚΥΑ ΔΥΓ3α/Γ.Π.32221/2013 (Gov. Gazette 1049/Β/29.4.2013).

5. In exceptional and special cases that relate to the unobstructed distribution of medicinal products and the protection of public health and patients, the competent service of EOF may file justified suggestions for the application of special criteria in order for them to be approved by a ministerial decision, upon the consent of the Prices Committee.

6. In case the Reference Medicinal Product of a generic, has a different package or strength, then reduction of the package or strength is effected, in accordance with the provisions of this article. A respective reduction is also effected in case the original has a price in another form or other strength.

Article 6:
Pricing of reference medicinal products under protection (on-patent)

1. The maximum producer's or importer's price (ex-factory) of the reference medicinal products under protection is defined as the average of the three lower prices of the EU member-states which publish reliable data. Maximum prices are regularly revised downwards, each time a prices bulletin is published. In order for a medicinal

product to be priced for the first time, it must have been priced in at least three EU member-states.

2. In order for the prices of the reference medicinal products to be determined, the competent department of EOF conducts an investigation in the member-states of the European Union, where data exist and is published by the competent authorities. It also investigates the agencies of these countries and the official or reputable European agencies. Access to the said sources for the collection of data is made via designated websites of the official sources of each EU member-state and/or via the official and reputable agencies such as the EURIPID and OBIG and the competent department of EOF is each time obliged to announce the said sources. During the investigation, any price available is sought (ex-factory, wholesale, retail). Special emphasis must be shown so that the prices are comparable and corresponding. In the case of special medicinal products such as orphans, hospital prices must not be deemed as wholesale or retail prices and vice-versa.

3. Conversion of prices from retail or wholesale to ex-factory and in Euro is made with the methodology and the coefficients announced by the competent department of EOF and published at its website, together with any other useful information and data that was used in the determination of the prices, so that it can be reproduced by any party interested. The exchange rate used, is the one published by the Bank of Greece, on the first business day of the two-month period preceding the issue of the Prices Bulletin. The necessary data for the determination of the price is: (a) the name of the medicinal product, b) the active substance, c) the active substance strength, d) the pharmaco-technical form, e) the package, f) the ATC classification, g) the person in charge for its marketing, h) the price(s) and i) the expiration date of the patent in Greece or in the EU member-states. All requests for pricing with the necessary supporting documents and other documentation are filed through EOF's Portal with the technical specifications each time announced through EOF's website.

4. EOF is also able to examine, apart from the data independently collected by its competent department, the data provided by the Marketing Authorisation Holders which is filed in the form of a statement with the respective information in the Data and Prices Research Sheets, which have been designed for the purposes of gathering all data required for the invoicing of the reference medicinal products. Data and Prices Research Sheet of Medicinal Products is filled in, signed and filed in the above manner, via EOF's portal, by the MAH of each medicinal product and serves as a solemn declaration, thus entailing all legal liabilities and sanctions provided for by the laws in case of false statements. In addition, in case erroneous data is filed or data is concealed, sanctions may also be imposed by the Minister of Health, in accordance with article 69 of law 3984/2011, following the granting of opinion by the Prices Committee.

Article 7:
Pricing of reference medicinal products under no protection (off-patent)

1. The maximum producer's or importer's price (ex-factory) of the reference medicinal products after the expiration of the patent of the active substance, which was determined in article 1 above, is automatically reduced either to 50% of the last under protection price or to the average of the three lower prices of the EU member-

states, keeping the lowest between the said two prices. More specifically, for medicinal products with no generic for which sales have been realised in the market (unique medicinal products) the average of the three lower prices in the EU member-states applies. When a generic is sold in the market, the 50% reduction applies even if it is lower than the average of the three lower prices in the EU member-states. During the initial application of this decision, no increase of prices is permitted in the case of existing unique medicinal products where average of the three lower prices is higher than the existing price.

2. For the products for whose active substance the patent protection will expire after the publication of this ministerial decision as well as for those whose patent expired on 01.01.2012, the preceding paragraph applies. For all the above products, the existing prices will be reduced when the average of the three lower prices in the EU member-states is lower that their existing price and this will apply to any Prices Bulletin to be issued. For this reason, EOF takes into account before the issue of any Prices Bulletin, the average of the three lower prices in the EU member-states and proposes the implementation thereof, when it is lower than the existing price of these medicinal products.

3. For the products for whose the patent protection of active substance expired before 01.01.2012, horizontal reductions of prices apply, as defined in a Ministerial Decision, each time a Prices Bulletin is published. More specifically, for the first Prices Bulletin to be issued after the publication of this decision, the prices of all medicinal products prior to 01.01.2012 with an existing retail price of over Euro 12 per package are reduced by 10% on the wholesale price. Similarly, the prices of all products set out in the above paragraphs with an existing retail price ranging among €6.00 to €11.99, are reduced by 5% and the prices of the products with a price lower than €5.99 are reduced by 2.5%. In case the horizontal or other reduction of prices to be applied, reduce the price of a unique product below the average of the three lower prices in the EU member-states the MAH may request from the prices committee of EOF that the average of the three lower prices in the EU member-states be applied. The horizontal reductions of the prices of medicinal products with a price marginally above the aforementioned limits of €6.00 and €12.00, as well as the application of paragraph 1 on medicinal products whose patent protection expired after 01.01.2012, may not reduce their prices below the said limits, for one any only re-pricing. In the next re-pricing, the horizontal reduction provided for the category in which it has been included with the preceding reduction of prices, applies. The Ministerial Decision, which will have the force of a market police regulation, will regulate the remaining details for the application of this article.

Article 8:
Pricing of generics

1. The maximum price of the producer or importer-marketing authorisation holder (ex-factory) of generics is set to 65% of the price of the respective off-patent medicinal products, whose price is determined in accordance with the provisions of article 7 above. In case the reference medicinal product has a different strength or package, then an approximate conversion from a similar reference product is effected or in accordance with the provisions of paragraph 5 of article 5. Moreover, if no reference medicinal product exists for a generic in the Greek market, the price of the

generic is calculated based on the application of the preceding provisions in articles 6 and 7 for the calculation of the reference price and then reduction is effected based on the provisions hereof.

2. This regulation applies to all products that will obtain a marketing authorisation from the date this decision will be published, for generics which obtained a marketing authorisation from 01.01.2012 and after, and for all generics corresponding to active substances whose patent protection is no longer in force from 01.01.2012 and forth.
The new packages, forms and strengths of generics whose initial product marketing authorisation had been issued before 01.01.2012 are subject to the same pricing provisions with the generics that obtained a licence before the said date. The provisions of this paragraph for the prices of generics apply on the prices of the reference medicinal products that will result from the application of the provisions of article 7.

3. In addition, for the generics of the preceding paragraph, dynamic pricing applies. More specifically, for each €250.000 sales that correspond to producer's price in the year preceding the publication of the Prices Bulletin, the prices determined in accordance with the above are reduced, so that dynamic pricing can be applied, to a further 1%. The sales are assessed based on the sales data for the 12-months period before the issue of each Prices Bulletin, which (data) are collected by EOPYY or EOF. On the first application of this decision, the sales data of the last six months before the issue of the said Prices Bulletin are taken into account. The prices can only be reduced based on this rule. More specifically, ,if after a reduction that was based on the sales of the preceding period the sales in the next period are lower, this does not lead to the readjustment of prices at higher levels. On the contrary, if in one of the following periods the sales are much higher than the ones that led to the determination of the prices below the level set out in the preceding paragraph, the prices are proportionally reduced.

4. For all other generics which do not fall into the scope of the provisions of the preceding paragraphs, horizontal price reductions apply, as specified by a Ministerial Decision, each time a Prices Bulletin is issued. More specifically, for the first Prices Bulletin to be issued after the publication of this decision, the prices of all medicinal products not falling into the scope of the provisions of the preceding paragraph, with an existing retail price of over Euro 12 per package are horizontally reduced by 15% on the wholesale price. Similarly, the prices of all products set out herein, as well as in the above paragraphs with an existing retail price ranging among €6.00 to €11.99 are reduced by 5% and the prices of the products with a price lower than €5.99 are reduced by 2.5%. The horizontal reductions of prices of medicinal products with a price marginally above the aforementioned limits of €6.00 and €12.00, may not reduce their prices below the said limits, for one any only re-pricing. In the next re-pricing, the horizontal reduction provided for the lower category in which it has been included with the preceding reduction of prices. The Ministerial Decision, which will have the force of a market police regulation, will regulate the remaining details for the application of this article. The occasional reductions may not reduce the price of a generic lower that 65% of the price of the reference medicinal product, save the relevant request of the marketing authorisation holder.

5. Moreover, for generics of the preceding paragraph with a price exceeding Euro 12, a system of dynamic pricing and retrospective application of rebates is implemented. More specifically, for each percentile increase unit of their penetration in the market, their price will be reduced by one percentile unit and the respective retrospective rebate will be imposed. The first application of the specific provision will take place in July 2014. More specifically, the sales in quantities of 2014 will be compared to the sales in quantities of 2013 regarding the cluster of the positive list in which the product has been classified so as to assess the market share thereof. If there is increase of sales and of the market share, then the price will be prospectively reduced in the future and a rebate will be retrospectively imposed on the producer's price, based on the resulting new price. The sales are assessed based on the sales data available to EOPYY and EOF.

Article 9
Special case Medicinal Products Pricing

1. In the event of a change of the manufacturer of a medicinal product or the packager or both, the price that the said product had before the change is deemed as the maximum limit. In the event of a replacement or addition of a new 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 in accordance with the provisions of the Ministerial Decision No 113429 (Gov. Gazette 3117/B/09-12-2013).

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

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

3. As an exception, the forms of single-dose injectable preparations, sachets and eye solutions shall be calculated pro rata. In case of price determination of two or more strengths of the same medicinal product, if disproportionate prices result, the lowers price is taken into account.

4. The above provision will apply to the next prices bulletin, until EOF files a new documented proposal for the replacement of the above table and the methodology of reduction.

Article 10:
On-patent medicinal products produced in Greece

1. Medicinal products produced in Greece which cannot exactly correspond as to the pharmaco-technical form, to reference medicinal products authorised and priced in the domestic pharmaceutical market, obtain a price which 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 violations of applicable provisions; d) third-party commissions and other costs not related to the production or marketing of medicinal products. In order for the raw materials cost to be determined, the respective cost that results after the reverse reduction of the applicable or resulting price of the reference medicinal product with a similar pharmaco-technical form is taken into account.

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.

4. The maximum net profit margin shall be 8.5% of the total cost excluding depreciation, interest and third-party profits (contract manufacturing).

5. Until the issue of the prices bulletin of July 2014, EOF will collect the necessary data for the preparation of an updated list with the specific products and for the calculation of the prices, in accordance with the provisions hereof. On the first application of this decision and thereafter, for the reduction of the administrative work load that the constant evaluation of the cost elements of these medicinal products entails, EOF may propose justified special assessment criteria, such as for example, horizontal reductions of the existing prices of the specific medicinal products, based

on the pack price and the year the marketing authorisation was obtained, respective to those provided for in the preceding articles.

Article 11:
Administered medicines of high cost set out in law 3816/2010

1. EOF, in cooperation with EOPYY, suggests the revision of the list of administered medicines of par. 2 of article 12 of Law 3816/2010. The first part of the list includes medicinal products suggested only for hospital use, which may be only acquired by public and private hospitals with more than 60 beds. Public hospitals must proceed with the actions required so that the necessary sources for the coverage of these products are available in their budgets. The said products may be offered by the pharmacies of EOPYY for use in private hospitals with less than 60 beds without a pharmacy and only in very exceptional and rare cases, they can be supplied by EOPYY to public and private hospitals with a pharmacy. In the last case, a document of the Administration of the Hospital or the Clinic to the Management of EOPYY must have be previously sent (communicated also to the Ministry of Health) in which the inability to procure medicinal products will be documented and after the President of EOPYY grants the relevant order, the medicinal products will be offered by the pharmacies of EOPYY.

2. The second part of the list includes medicinal products whose use may commence in the hospital and continue outside of it. These medicinal products mainly concern severe diseases. The initial diagnosis and prescription must be performed mainly in hospitals, specialised medical centres or specialised physicians. Procurement and offer of these medicinal products may be effected by the pharmacies of hospitals, the pharmacies of EOPYY and the private pharmacies. EOPYY is procured the specific products under the same terms of procurement with the hospitals. In case the said products are offered by private pharmacies, the provisions of this decision apply.

3. By virtue of the decision of the Minister of Health, the manner of invoicing and offer may change and the said medicinal products may be sold at the ex-factory price to the wholesaler and then be subject to the same rebates, on the ex-factory price, which apply for all other medicinal products of the positive list which are offered through the pharmacies. In these cases, MAHs reserve the right, if they so decide, to offer these medicinal products from private pharmacies only in case of patients included in patients' registries. In these registries, patients must be assigned a unique code and a verification mechanism must be in force, in order to verify that the patient has indeed been administered the treatment. MAHs will state the said cases with an official statement to EOF, the distribution channel of the products set out in par. b of article 12 of Law 3816/2010 they select, so as to ensure the adequacy of the domestic market and the access of patients suffering from severe diseases.

4. Medicinal products set out in par. 2 of article 12 of Law 3816/2010, regardless of the network they are offered, are fully reimbursed by the insurance agencies and are offered to patients with no copayment. EOF and EOPYY are obliged within one month from the publication of this decision, to propose a revised list, keeping therein only the therapeutic schemes that strictly observe the criteria of the relevant provisions. When, for the medicinal products of the specific list, the protection period expires, and generics are available, EOPYY can classify them in clusters, with the

exception of the biological ones and the narrow therapeutic width or alternatively through the Committees thereof, to propose and compensate the beginning of the administration of the generic to new patients. EOPYY is also entitled to pre-approve the use of the specific medicinal products with high purchase cost or high annual cost of treatment, through the Committees thereof and offer them through its pharmacies. If the committees of EOPYY pre-approve the use of a specific medicinal product, this must also be the case for all medicinal products belonging in the said category. For the continuous service of insured persons, EOPYY is obliged, within the first six months of 2014 to develop an electronic system for the approval of the use of these medicinal products within three (3) business days from the date the relevant request was filed by the attending physician. EOPYY is also entitled to decide the pre-approval of the use or the purchase and administration by its pharmacies, of medicinal products with high treatment cost which are not necessarily included in par. 2 of article 12 of Law 3816/2010. Moreover, EOPYY is entitled to decide the exclusive provision of medicinal products with a very high treatment cost or rare (orphan) diseases, from its pharmacies.

5. EOPYY and hospitals are procured the specific products in accordance with the relevant provisions at a hospital price -6.5%. When these medicinal products are provided by private pharmacies, a 16% margin applies for medicines with a Special Wholesale Price which is less than €200 and a €30 fixed fee of the pharmacist for medicinal products with a Special Wholesale price exceeding €200. The percentage provided for in par.2 of article 12 applies to the hospital price at the calculation of the Special Wholesale Price. Especially for medicinal products with new active substances, the provisions of the above article apply. The additional 5% is added to the discount in case of procurement by EOPYY or the rebates respectively in case the medicinal products are offered by private pharmacies.

Article 12:
Biologic factors and orphan medicinal products

1. The maximum producer's or importer's price (ex-factory) of all biological products (blood products, biotechnological products, vaccines, bio-similar products and other biological products) is set as the average of the three lower prices in the EU countries. The resulting prices may be less or equal with the applicable ones.

2. Biological factors as related to each other, but also as related to the bio-similar products are not deemed of direct exchangeability. The selection regarding the therapy to be prescribed falls under the exclusive jurisdiction of the physician. During the prescription of biotechnology products, physicians must prescribed within the specific indications, taking into account the relevant efficacy of the biotechnical therapies and the therapy cost. EOPYY may through its Committees, establish criteria and conditions for prescribing the biological factors. For very special prescription cases which lie outside the scope of the approved indications, the provisions of the Ministerial Decision No ΔΥΓ(3)α/οικ.Γ.Υ.154 /29.02.2012 (Gov. Gazette 545/B'/01.03.2012) apply.

3. Orphan medicinal products may be priced even if prices are offered in only two other European countries. EOF's website must have a link of the European Medicines Agency in order to present the official European registry of orphan medicinal

products. After pricing, the orphan medicinal products may be posted for 30 days on the positive list of medicinal products. EOF must appoint a committee which will propose actions for adopting incentives that will promote the availability of orphan medicinal products in accordance with the European standards.

Article 13:
Rebates

1. An additional 2% is added to the existing 9% rebate for the inclusion in the positive list, for medicinal products containing active substances that have been classified by themselves in cluster in the positive reimbursement list of article 12 par. a of Law 3816/2010.

2. An additional 1.5% rebate is added as a discount on the hospital price for all medicinal products of the special list of medicinal products for severe diseases set out in par. b of article 12 of Law 3816/2010, which EOPYY and the hospitals are supplied.

3. Especially for the medicinal products with new active substances which are priced for the first time, apart from the fixed entrance fee, an additional 5% rebate or a discount is accordingly introduced, as the case may be, for the medicinal products included in the provisions of the preceding paragraphs respectively, as a percentile entrance fee for the inclusion of all new medicinal products under a reimbursement regime, for a period of one year after their inclusion date. This provision applies to all medicinal products with new active substances that will be included in the positive list from the date this decision will be published and forth. The amount is set as an additional discount, in case it is granted to the hospital or by a pharmacy of EOPYY and in parallel with the rebates of paragraph 4 of this article, when it is granted by private pharmacies. If the MAH does not fully comply, the medicinal product is removed from the positive list. For medicinal products with new active substances which will obtain a marketing authorisation from 01.01.2014, this decision applies, only when they obtain a price and reimbursement within the time period set out by the relevant directive of the EU.

4. The additional escalated rebate is determined in the following table, with regard to the total sales volume of the medicinal products for the preceding three-month period:

Three-months total volume per active substance medicinal products	Additional rebate
100,000-400,000	2%
400,001-800,000	4%
800-001-1,200,000	6%
1,200,001-1,600,000	8%
1,600,001-2,000,000	10%
Above 2,000,000	12%

5. The ex-factory prices are used for the calculation of the said rebate. The said percentages may be fixed by a Ministerial Decision in accordance with the achievement of the pharmaceutical targets. This article enters into force from

1/1/2014. The rebates of marketing authorisation holders to the social insurance agencies and EOPYY are regulated by the applicable provisions. For pharmacies, the existing rebates apply.

Article 14:
Reimbursement of medicinal products

1. After the revision of the prices or after the approval of the new prices of medicinal products, the positive list and the respective reference are revised within 30 days. The new generics are automatically included in the list, provided that the reference medicinal products (off-patent) are also included therein.

2. In the next revision of the list, the reference price of each cluster must be based on the average of the three cheaper generics of each cluster with a volume market share of all strengths and packages over 4% in the said cluster, if it extracts prices lower that the existing system.

3. When an objection is filed, a written and justified answer for the final decision to the relevant entity in charge of the marketing must be filed by the competent Committee of EOF.

4. When medicinal products are excluded from the positive list of reimbursed medicinal products due to non-payment of the rebates or the claw back, this does not affect the calculation of the reference and reimbursement prices until the next revision of the positive list.

5. Medicinal products which, by decision of the Positive List Committee are shifted from the positive to the negative list or to the list of OTC medicinal products or vice versa, are priced, before their shift, first in accordance with the provisions in force from time to time that correspond to the medicinal products of the category in which they are reclassified. The prices of medicinal products which, upon the MAH's request, are shifted from the positive to the negative list of prescribed medicinal products and their cost is not reimbursed, are determined based on the price of the average of the three lower prices of the respective products of the EU Countries. If they are re-included upon the MAH's request in the positive list of prescription medicines, the occasionally applicable provisions hereof apply.

Article 15:
Prescription Protocols

By virtue of the decision of the Minister of Health, a 5-member National Committee for monitoring the pharmaceutical expenditure and the application of the therapeutic prescription protocols is established, with the participation of a representative of EOPYY, which has as its object: a) The selection of the diseases and conditions for which prescription therapeutic protocols will be developed (diagnostic and pharmaceutical) with epidemiologic incidence criteria (prevalence and impact) and the need to intervene in order to adequately cover common diseases/conditions and hospitalisation b) The determination of a framework and monitoring of an audit mechanism for the implementation of the therapeutic protocols (audit indexes), c) The proposing of measures to the Minister of Health in case of transgression of the

therapeutic protocols and over-prescribing, d) the determination of the special therapeutic categories for the development of patients' registries, the framework for the functionality of the registry and the access thereto for auditing, regulatory and epidemiologic purposes, e) the making of suggestions for the improvement of the whole system, with regard to needs and malfunctions that may occur and f) the management of any objections of any person having relevant legal interests.

2. In order for the work of the Committee to be implemented, all agencies involved are obliged to provide any information necessary. For the more effective function of the Committee, it may, with the relevant decisions thereof, form special committees or work groups (e.g. oncology committee, in order to propose a list of bio-indexes and tests, as well as the conditions required in order for oncology and biologic products to be prescribed).

3. The responsibility for the preparation of therapeutic protocols, following the relevant invitation of the National Committee, lies with the scientific societies of medical specialties and specialties recognised by the KESY, in cooperation with the Medical Society of Athens, which is responsible for the co-ordination of the development of therapeutic protocols and digital presentation thereof, as well as the support of the audit mechanism and training of physicians in the application thereof, with the cooperation of the special scientific medical societies. The scientific societies are obliged to for Work Groups for this purpose, ensuring the procedures of the strong scientific consent in the development of the therapeutic protocols, with the participation of Unions of patients. In case of denial or inactive participation of the scientific societies, respective Work Groups according to the merit may be established, upon the suggestion of the National Committee.

4. KESY is the competent agency for the approval of the therapeutic protocols and for determining the framework for the update thereof, at least once per year, with the incorporation of all newer scientific data.

Article 16:
Goals and Monitoring of Prescription

1. By virtue of the decision of the President of EOPYY, which will be published within one month from the date this decision is published, the prescription limits for each physician cooperating with EOPYY are determined for 2014. More specifically, the monthly expenditure of all prescriptions of each physician may not exceed 80% of the average monthly expenditure thereof during 2013. For this reason, EOPYY calculates the average monthly expenditure per physician for 2013 and sets the limits of the monthly prescription expenditure per physician for 2014. HDIKA adjusts the electronic prescription system so that the physician will not be able to prescribe per month, medicinal products whose total expenditure exceeds by 20% the monthly limit set for each physician. The physician may exceed the said limit for two (2) months, however, in the third month the system does not allow him/her to prescribe a total amount above the monthly amount, less the transgression of the preceding two months. The physician may in the following month continue with the same terms that applied for the preceding three-month period. The new-entrants are permitted to have expenditure respective to the average of their specialty . The limits of the expenditure per physician are redefined during the year, in proportion to the work produced by the

said physician and the course of the total pharmaceutical expenditure, especially for the categories in which new medicinal products are included in the positive list.

2. In addition, by decision of the President of EOPYY which will be published within one month from the date this decision is published, limits for the prescribing of medicinal products may be specified, per specialty or therapeutic category, in off-patent active substances, together with mandatory targets for prescribing generics. For the calculation of the targets per specialty, the prescriptions issued per specialty are calculated, together with the availability of generics in each cluster, so as to potentially assess the prescriptions that may concern no protected medicinal products or generics. HDIKA will re-adjust the electronic prescription system so that the physician cannot exceed the enacted limit. In addition, HDIKA is obliged to readjust the system so that the physician is able to suggest the cases in which a generic must be administered. If the physician suggests a generic upon the prescription, the offer of a non-generic medicinal product by the pharmacy is prohibited. If the patient selects a medicinal product with a price that exceeds the reimbursement price, then he/she will pay the total difference that exceeds. The prescription target for generics must be by average, set to 60%. EOPYY may establish a bonus and incentives for physicians who comply with the above target.

3. EOPYY's administration undertakes to perform the necessary actions and develop the knowledge, systems and specialisation required in order to implement price-volume and risk allocation agreements with the producers, especially in the cases of selected expensive medicinal products, such as biological ones. In addition, EOPYY and HDIKA, in cooperation with the competent committee, will see that until June 2014, at least the 20 most costly therapies are included in the prescription system. In addition, EOPYY and HDIKA will develop registries for the monitoring of very expensive and orphan medicinal products.

4. Until the necessary infrastructure is developed, EOPYY may purchase consultant services from the appropriate public or private agencies, who will assist in its services for the better monitoring and thorough analysis of pharmaceutical expenditure, the analysis of compliance with the therapeutic protocols and relevant activities aiming at the more effective and efficient use of medicinal products.

5. For the development of the targeted-therapy, within one month from the publication of this decision, the oncology committee is called to propose a list of bio-indexes, tests and conditions required in order for oncologic and biologic products to be prescribed. In parallel, reimbursement prices for these indexes must be filed, so as to be included in the EKPY and serve as a prerequisite, upon the decision of the President of EOPYY, for the administration of oncologic medicinal products.

Article 17:
Issues of the National Organization for Medicines

1. EOF undertakes to perform all necessary actions, so that the procedures for the approval of pharmaceutical products, will be performed in accordance with the time schedules provided for by the relevant legislation and also to constitute the competent authority which will undertake the mutual acknowledgment of licensing.

2. EOF must file to the competent Directorate of the Ministry every six months a perspective plan for audits and tests in various pharmaceutical substances and productive production units and retrospectively the results of all audits of the preceding six-month period.

3. Within six months from the publication of this Ministerial Decision, EOF must proceed with all necessary actions for the development of software, either from its services or in cooperation with external agencies to be used, so that the pricing and reimbursement procedure for medicinal products is automated.

4. EOF must establish within 15 days from the date of publication hereof, a five-member experts committee which will anew assess the present list of OTC Medicinal Products, in comparison with the applicable ones in the other member-states of the European Union. For products not included in the present OTC list but are included in at least three EU Countries, the relevant documented justification must be provided for their non-inclusion in the national list. Products included in OTC lists in 10 member-states of the EU are obligatorily listed in the OTC list. The revised list of OTC Medicinal Products is approved by the decision of the Minister of Health. The committee has a term of office of two years which can be renewed, it is appointed by the President of EOF and the Chairman thereof is a Professor of a Pharmaceutical or Medical School with specialty and experience in the specific object.

5. EOF must undertake the relevant actions, in cooperation with EOPYY, for the development of the proper infrastructure and know-how which are required for the Health Technology Assessment), the participation in respective networks (EUNETHTA) and the development of relationships with the competent European authorities for the exchange of information and data.

Article 18:
Claw Back 2014

1. The budget for the pharmaceutical expenditure for the total social insurance agencies cannot exceed the approved in the 2014 budget amount. The above amount is allocated proportionally per Social Insurance Agency, with regard to the approved budget thereof. The monthly expenditure of each Agency must not exceed 1/12 of the sum that has been recorded in the annual Budget thereof and corresponds to the pharmaceutical healthcare, which excludes expenses that relate to serums, vaccines, blood derivatives, blood sugar stickers, consumables, as well as the EKAS and in general everything that does not relate with the pharmaceutical products.

2. The excessive amount is calculated on a six-month basis and in case, at the end of each six-month period, the total pharmaceutical expenditure has exceeded the predetermined amount, the balance is sought and paid by the pharmaceutical companies, in accordance with the relevant provisions. In order to monitor the course of the pharmaceutical expenditure in relation to the targets set, the amount of the transgression may be defined in accordance with the historical trends and the expected time return of the measures and administrative interventions that have already set in motion. The above does not affect the claw back of the six-month period, which must be paid.

3. More specifically, as regards EOPYY, the monthly expenditure, the claw back and the manner of calculation and payment thereof is made in accordance with the existing provisions. In addition, it is possible, if the relevant decision is adopted, for an expenditure target to be set per ATC2 category for the total or for specific categories of medicinal products, as well as per ATC5 in specific cases of medicinal products and special arrangements and regulations may apply, in case of transgressions of the enacted targets. The target may be set on the basis of the expenditure for 2013 in the occasional category, which may later be reduced for 2014 by the amount that corresponds to the percentile reduction of the total pharmaceutical expenditure. Alternative criteria may be set on a case-by-case basis, such us epidemiological ones.

4. The above amounts apply for all medicinal products reimbursed by the Social Insurance Agencies, including those set out in par. 2 of article 12 of Law 3816/2010. EOPYY may decide the exclusive offer of medicinal products with very high treatment schemes cost or rare (orphan) diseases or high cost from its pharmacies του.

Article 19:
Monitoring the Expenditures of ΕΟΠΥΥ

1. By virtue of the decision of the President of EOPYY, which will be published within one month from the date this decision is published, expenditure limits for diagnostic and laboratory tests may be set, and/or limits of other services and interventions for 2014 per physician prescribing for EOPYY, with a similar methodology as the one set out in article 15 hereof. More specifically, the limits may concern expenditures for prescribing specific diagnostic and laboratory tests or groups thereof or the total prescriptions granted by a physician. These limits per physician will be reduced compared to those of 2013, to the amount that corresponds to the reduction of the budget of EOPYY for 2014, for the specific category of expenditures. The average per specialty will correspond to the new-entrants. It is possible that these limits are redefined during the year.

2. By virtue of a decision of the President of EOPYY, a five-member Committee for the development and implementation of laboratory and diagnostic protocols is established, whose object is: a) The selection of the tests and conditions for which therapeutic prescription (diagnostic) protocols will be developed, b) The determination of a framework and monitoring of a control mechanism for the application of the protocols, c) The proposal of measures to the President of EOPYY in case of transgressions and over-prescribing, d) The filing of proposals for the improvement of the system in whole, with regard to the needs and malfunctions that will occur, e) The management of any objections by any person having legal interest. In order for the tasks of the Committee to be performed, all parties involved are obliged to provide any information required. Scientific societies of medical specialties recognized by the KESY may contribute, following the relevant invitation, to the preparation of the diagnostic protocols, in cooperation with the Athens Medical Society, which is responsible for coordinating the development of the therapeutic protocols and their digital imaging, as well as to support the control mechanism and training if physicians in their application, with the cooperation of special scientific medical societies. By decision of the President of EOPYY, KESY may constitute the

competent agency for the approval of the above protocols and for the determination of their updating framework, at least once per year, with the incorporation of all newer scientific data. The above protocols must be incorporated in the electronic system for the monitoring of the prescription of tests and will be linked with data and the diagnosis of the patient, so that limits will be set and over-prescription will not be permitted, as well as the unnecessary use of tests and services. In addition, the list with the services reimbursed by EOPYY will be assessed, in accordance with the due and documented medical practice, the international literature and the applicable European standards.

3. By virtue of a decision of the President of EOPYY, which will be published within one month from the date this decision will be published, expenditure budgets per diagnostic centre, laboratory and clinic may be determined, for the total or part of the tests and services rendered to insured persons of EOPYY. The occasional budget for the total of the agency or for part of its services, corresponds to the expenditure for the agency or the services of the agency for 2013, reduced by the respective reduction of the budget of EOPYY in the specific category of expenditures for 2014. The budget set for 2014 will concern the conduct of at least an equal number of tests or hospitalization and services in 2014 with the respective number of 2013. If the provider exceeds the specific defined budget, then a rebate will apply to its turnover, which will be determined by decision of the Minister of Health, upon the relevant suggestion of EOPYY.

4. By virtue of a decision of the Minister of Health, following the suggestion of EOPYY, which will be published within one month from the date this decision is published, new reimbursement prices for tests and services in private clinics and laboratories may be defined. These prices will reflect and be connected with the adequacy of infrastructures and the qualitative classification of the providers, as well as the quantity of the services provided, with an ultimate future purpose being that the efficacy of services is taken into account. For this reason, EOPYY will develop a system of qualitative assessment and classification of the service providers to EOPYY's insured persons.

5. EOPYY will develop a department of comparative assessment and analysis, for the purposes of providing continues and thorough assessment of the cost and efficacy of the quality of services of alternative public and private providers and the implementation of negotiations and volume-prices and risk allocation agreements. In addition, it investigates, assesses and alters the reimbursement prices, based on the developments in technology and the effects at the production cost of health services.

6. The budget of the expenditure for tests and hospitalization in the private sector of EOPYY may not exceed the approved amount in the 2014 budget. The above amount is proportionally allocated, in accordance with the approved budget thereof. The monthly expenditure must not exceed 1/12 of the sum recorded in the annual Budget thereof. The excessive amount is calculated on a six-month basis and in case, at the end of each six-month period, the total expenditure has exceeded the predefined amount, the balance is sought from the providers in accordance with the relevant provisions. In order to monitor the course of the pharmaceutical expenditure in relation to the targets set, the amount of the transgression may be defined in accordance with the historical trends and the expected time return of the measures and

administrative interventions that have already set in motion. The above does not affect the claw back of the six-month period, which must be paid.
For the calculation of the transgression per provider, a mathematical form is used which reflects by half a) the market share of the provider in his category and by the other half b) the historical increase of sales through time.

Article 20:
Pharmaceutical Expenditures of Hospitals

HDIKA, in cooperation with the General Secretariat of the Ministry of Health, the YPE and Hospitals, plans and gradually implements within 2014 the expansion of the electronic prescription system for medicines provided to hospitals either on an internal or an external basis, for the total of patients of for special categories, such as non-insured persons and indigent, aiming at better monitoring and controlling pharmaceutical expenditures.

This decision must be published in the Government Gazette.

Athens, 14 - 01 - 2014

THE MINISTER

SPYRIDON – ADONIS GEORGIADIS

Internal Distribution:

1. Office of the Minister of Health
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