GOVERNMENT GAZETTE
OF THE HELLENIC REPUBLIC

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DECISIONS

No Γ.Π./οικ.61771

Provisions on the pricing of medicinal products

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. 96/1973 mainly article 17 as amended and in force (Gov. Gazette A' 172).
4. The provisions of the L.D. 136/1946 "for the Market Police Code" (Gov. Gazette A' 298), as amended and in force.
5. The provisions of article 13 of Law 3408/2005, as amended and in force (Gov. Gazette A 272).
6. The provisions of Law 3842/2010 (Gov. Gazette A 58) as amended and in force.
7. The provisions of article 4 par. 2 of Law 3899/2010 ((Gov. Gazette A 212), for the amendment of VAT Code.
8. 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 and Law 1965/1991 (A 146). .
9. The provisions of the P.D. 95/2000 "Organisation of the Ministry of Health and Welfare" (A΄ 76), as amended and in force.
10. The provisions of articles 38, 39, 40 and 51 of Law 3918/2011 (Gov. Gazette A 31) as amended and in force.
11. The provisions of articles 11, 16, 17, 19, 20, 21 and 23 of Law 4052/2012 (Gov. Gazette A 41) as amended and in force.
12. The Joint Ministerial Decision (ΚΥΑ) 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.
13. 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).
14. The Ministerial Decision No ΔΥΓ3(α)/οικ.94274/28.9.2012 "Application of article 15 in Law 4052/2012" (Gov. Gazette B 2675).

15. 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 40 and 51 of law 3918/2011 (A΄31).
16. The provision of article 22 of Law 4213/2013.
17. Article 34 of Law 4025/2011 (Gov. Gazette 228A).
18. The P.D. 89/2014 (Gov. Gazette A 134/2014) "Appointment of Ministers, Alternate Ministers and Deputy Ministers".
19. The Order of the Minister of Health under protocol No 4120/11-07-2014.
20. The fact that no expenditure is incurred against the State Budget from this decision, we decide:

WE DECIDE

Article 1:
Definitions and Categories 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. The invoicing method is different when a reference medicinal product is no longer protected (on-patent). Exclusively and only for pricing purposes, a medicinal product is no longer protected (off-patent) when the documentation that the protection period of its active substance has expired, either in Greece or in other member-states 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.
If there are reliable data, the on-patent period for the active substance supersedes the protection period if it expires at a posterior time. The above-mentioned separation of the reference medicinal prices and the definition of the protection period are exclusively and only made for pricing purposes of these medicinal products and cannot be used by third agencies for other purposes.

2. 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 pharmaco-technical forms administered Per Os with direct release are deemed as the same pharmaco-technical form. For the needs of pricing, the provisions for pricing of generics also includes the cases of article 12 of the Joint Ministerial Decision (KYA) No ΔΥΓ3α/Γ.Π.32221/2013 (Gov. Gazette 1049/B/29.4.2013). For the case of the pricing of medicinal products, which obtain license by virtue of article 14 of the Joint Ministerial Decision (KYA) No ΔΥΓ3α/Γ.Π.32221/2013 (Gov. Gazette 1049/B/29.4.2013), 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”. Hybrids are priced based on the provisions 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) are priced based on the average of the three lower prices of the member-states of the European Union, if they are imported and based on the provisions for domestic production, if they are domestically produced. The reference medicinal product in the above cases is priced as unique.
3. The characterisation of a medicinal product as a reference medicinal product, as under or no protection, or as generic is made by EOF, who grants its opinion and recommends the pricing of special cases of pharmaco-technical forms. Exclusively and only for pricing purposes according to the provisions hereof, which concern the Marketing Authorisation Holders (MAHs), it is deemed that they concern agencies deemed equal therewith, such as importers, manufacturers, packagers, agents and distributors.

Article 2:
Prices of Medicinal Products

1. The maximum producer’s price (ex-factory) is the sale price by the marketing authorisation holders (MAHs) to the wholesalers and it is calculated in accordance with the provisions hereof. The producer’s price is based on the wholesale price reduced (a) for prescription medicinal products which are not reimbursed by the Social Insurance Agencies with a price up to €200 by 4.67% and with a price over €200.01€ by 1.48%, b) for prescription medicinal products not reimbursed by the Social Insurance Agencies, by 5.12% and c) for the non-prescription (OTC) medicinal products by 7.24%.

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 ex-factory as defined in par. 1 of article 3 hereof.

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 as set out in par. 2-4 of article 3 hereof and the applicable Value Added Tax (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, State 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. The maximum hospital price shall be determined on the basis of the ex-factory price reduced by 8.74%.

5. The MAHs may request reductions from the maximum ex-factory prices, for all categories of medicinal products, which are immediately accepted with a supplementary prices bulletin, which is approved by the decision of the Minister of Health, following the suggestion of the Directorate of Medicinal Products and Pharmacies of the Ministry, to whom the request is filed. The Marketing

Authorisation Holder 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.

6. MAHs may sell OTC to the wholesalers at prices lower than the maximum ones, provided that such condition is recorded on the sales invoice. Wholesalers may sell OTC medicinal products to the pharmacists at prices which are lower than the maximum ones, provided that such condition is recorded on the sales invoice and respectively, pharmacists may sell the said medicinal products at prices lower than the maximum ones, provided that such condition is recorded on the sales invoice.

Article 3
Profit Margins (mark up)

1. For wholesalers, gross profit margins (mark up) shall be determined as follows: a) for non-prescription medicinal products (OTC), as a percentage of 7.8% on the maximum net ex-factory price; b) for prescription medicinal products not reimbursed by social security agencies, as a percentage of 5.4% on the maximum ex-factory price; c) for all medicinal products reimbursed by social security agencies, as a percentage of 4.9% on the maximum net ex-factory price when it is equal to up to €200 and d) for all medicinal products reimbursed by social security agencies as a percentage of 1.5% on the maximum net ex-factory price, when it is above €200.01.

2. For pharmacies, the mark up shall be determined as follows: a) for non-prescription medicinal products (OTC), as a percentage of up to 35% on the wholesale price; b) for prescription medicinal products not reimbursed by social security agencies, as a percentage 35% on the wholesale price; c) for all medicinal products reimbursed by social security agencies in accordance with the following table:

Wholesale price (€)	Gross Profit Margin (mark up) of Pharmacy
0-50	30.00%
50.01-100	20.00%
100.01-150	16.00%
150.01-200	14.00%
200.01-300	12.00%
300.01-400	10.00%
400.01-500	9.00%
500.01-600	8.00%
600.01-700	7.00%
700.01-800	6.50%
800.01-900	6.00%
900.01-1000	5.50%
1000.01-1250	5.00%
1250.01-1500	4.25%
1500.01-1750	3.75%
1750.01-2000	3.25%
2000.01-2250	3.00%

2250.01-2500	2.75%
2500.01-2750	2.50%
2750.01-3000	2.25%

3. The above mark up percentages constitute the maximum limits in the case of OTC medicinal products, both for the wholesalers and the pharmacists and they voluntarily reduce them or offer the specific medicinal products in lower prices, provided that such discount is recorded on the sales invoice.

4. The above mark up percentages concern all reimbursed medicinal products sold by private pharmacies, including the medicinal products set out in par. 2 of article 12 of Law 3816/2010. par. 3 of the Ministerial Decision 45001/Gov. Gazette 1435/04.06.2014 is abolished. When these medicinal products are sold by private pharmacies and EOPYY or any other public agency does not cover the relevant expenditure, the pharmacist's mark up is determined in accordance with the percentages of the above table and for medicinal products with a price higher than €3000 a mark up of 2% us fixed.

Article 4:
Discounts and Credits

1. Marketing Authorisation Holders may offer additional discounts on the hospital price, without any restriction for the medicinal products supplied to the State, State Hospitals, the Social Care Units set out in Article 37 of Law 3918/2011, the pharmacies of EOPYY and the pharmacies of private clinics with over 60 beds, provided that any such discount is recorded on the sale invoice.

2. MAHs may grant discounts without any restriction on the ex-factory price for OTC medicinal products and for the medicinal products set out in par. 2 of article 12 of Law 3816/2010 and up to 10% on the wholesale price for prescription medicinal products sold to medicinal products traders, pharmacies and co-operatives, provided that any such discount is recorded on the sale invoice.

3. Wholesalers may grant a discount of 10% for the prescription medicinal products and unlimited discounts to pharmacists for the OTC medicinal products and for the products set out in par. 2 of article 12 of Law 3816/2010 provided that any such discount is recorded on the sale invoice. Wholesalers may sell OTC medicinal products at a discount from the maximum price, provided that any such discount is recorded on the sale invoice.

4. MAHs are obliged to grant to pharmacies, medicinal products traders and co-operatives at least a two-month credit, provided that any such credit is recorded on the sale invoice. Wholesalers are obliged to grant to pharmacies and co-operatives at least a two-month credit, provided that any such credit is recorded on the sale invoice. The OTC medicinal products are excluded from the scope of application of the provisions of this paragraph.

5. The verification of the non-observance of the terms of the preceding paragraphs, leads to the imposition of the sanctions provided for in the Market Control Code.

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. EOF announces the date based on which the general re-pricing of medicinal products takes place. New medicinal products are priced after the marketing authorisation is obtained and the application is filed within the timeframe set out in the Transparency Directive, as this has been transposed into the National Law. In particular, in the case of generics, prices are published within 30 days from the date the application of the marketing authorisation holder was filed and in the case of all other medicinal products, within 90 days from the date the application of the marketing authorisation holder was filed. EOF is obliged to prepare a prices bulletin per month for the pricing of new generics and per every three-month period in the case of new reference medicinal products. For this reason, supplementary prices bulletin are issued. During the general re-pricing, EOF is obliged to include all generics for which a pricing application was filed 30 days before the re-pricing commencement date and for all reference medicinal products for which a pricing application was filed 90 days before the re-pricing commencement date. After the general re-pricing in the beginning and the middle of the year, EOF is obliged to proceed with actions so that supplementary prices bulletins will be issued, according to which, all new generics for which an application was filed 30 days before the issue of the relevant prices bulletin commences and all new reference medicinal products for which an application has been filed 90 days before the issue of the relevant prices bulletin commences, will be priced. For the purposes of smooth organising and operation of the market and for the continuous access of patients to the new medicinal products, 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 ex-factory prices and the exchange rates have been calculated at a later stage.

3. When calculating the final prices of new medicinal products to be priced, countries may be used in which a product was sold up to the date the prices were evaluated by the competent prices department of EOF and not strictly on the date the procedure was initiated by EOF. After the first application of this Ministerial Decision, EOF may, at the date the procedure for the issue of a general prices bulletin or a prices bulletin for new medicinal products was initiated, by a documented decision thereof which is announced, temporarily exclude from the reference countries cases for which

special recommendations have been granted or other special reasons concur that establish the need to exclude the said reference countries. For all products priced for the first time, there should be, before their pricing, a classification by the competent bodies, to products of the positive list, products of the negative list and products of par. 2 of article 12 of Law 3816/2010. The maximum ex-factory price for the OTC medicinal products as well as the products included in the netagive list is determined based on the same pricing provisions with those that apply to the prescription medicinal products. In case the interested MAH applies for a classification, as regards its classification, in the negative list, the relevant opinion must have been granted by the competent body of EOF. Medicinal products which, by decisions of the Positive List Committee shift 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 occasional provisions that correspond to the medicinal products of the category in which they are reclassified. The prices of the medicinal products which, upon the application of the MAH, shift from the positive to the negative list of prescription medicinal products and whose cost is not reimbursed are determined based on the price of the average of the three lower prices of the respective products in the member-states of the EU. If they are re-listed, upon application of the MAH, in the positive list of prescription medicinal products, then the occasionally applicable provisions hereof apply. Before the filing to the Minister of Health, EOF sends the prices extracted based on the data it has collected, to each MAH separately for any comments. For generics, the reference prices from which the prices of generics are concluded can also be sent upon request. 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 to the competent Directorate of the Ministry and publishes it. Upon the first application of this Decision, the prices of medicinal products included in the negative list and of the OTC list are not re-priced.

4. Objections on the published prices, if they have been timely filed, are all answered by the competent department of EOF in writing, with the proper justification and documentation in accordance with the applicable provisions and if they are accepted, they are incorporated in the supplementary prices bulletin which is obligatorily issued within 20 days from the date the initial prices bulletin was posted and the objections period elapsed. No increase is permitted in each revision of prices. New prices may be equal or less than the applicable ones. Nevertheless, increases are accepted in case of corrections of errors which (corrections) are included in the supplementary prices bulletin issued on the dates set out by the relevant legislation after the occasional general prices bulletin or the prices bulletin for new medicinal products.

5. At any time, MAHs may request further reductions of the prices by the competent Directorate 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. Prices are not published for all medicinal products with no sales within the past three (3) years, before the date the prices revision process commenced. The terms sales include the exports if they have been realised within the three-year period provided for by the Decision. Exports must be proven based on the relevant data filed by the MAHs at EOF's database. 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/B/29.4.2013) and evaluated by the competent department of EOF as new applications for pricing. Consequently, the MAHs must file all necessary supporting documents accompanying the new applications, including the relevant surety bonds.

6. In exceptional and special cases that relate to the unobstructed sale 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. If a medicinal product shifts from the negative to the positive list, then the provisions hereof apply. A condition for the inclusion of a marketed medicinal product in the positive list is the re-pricing thereof in accordance with provisions that applied in the last prices bulletin for the re-pricing of medicinal products. The parenteric solutions that concern only serums-electrolytes, uniform prices are determined, based on the active substances, strength, packages and other cost elements. On the first application of this decision, the prices of the parenteric solutions sustain the reductions provided for in proportion to their price. The maximum producer's (ex-factory) price of all biological and bio-similar 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 equal or less than the applicable ones. Exceptionally for blood derivatives, the resulting prices cannot be less than the average of the three lower prices of the EU countries. For the purposes of protecting public health and in order not to endanger the adequacy of the said products for the patients' needs, blood derivatives are excluded from the imminent pricing. Orphan medicinal products may be priced even if prices are available in only two other EU countries. Especially for the orphan medicinal products, for which the ex-factory prices are identified with the hospital prices in the reference countries, the MAHs must produce the respective supporting documents to EOF so that it will be respectively taken into account during the calculation of the prices. The resulting prices may be equal or less than the applicable ones.
7. For the OTC medicinal products already marketed in Greece, the provisions of this Decision apply. The new OTC medicinal products that will be marketed and for which similar medicinal products as to their active substances, strength and pharmaco-technical form are already marketed, will be dispensed at the same or lower prices than that of those already marketed in accordance with the provisions hereof, while those with active substances that are not available in the Greek market, are priced based on the average of the three lower prices of the EU member-states and next, the provisions of this Decision apply. No increase of the prices of the OTC medicinal products is permitted until 01.01.2016.

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

1. The maximum producer'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. No increase of the prices of existing medicinal products is permitted, save in the cases of corrections of pre-existing errors.

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 to the agencies of these countries and to 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 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 special cases of 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 to wholesale or 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 collecting 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. Filing of requests, sheets, queries, data as well as any other communication of the pharmaceutical companies with the Department of Prices of Medicinal Products of EOF is also possible via the email newdrugs042013@eof.gr. In case of pricing of new medicinal products for which the determination of their price is provided for based on the average of the three lower prices of the European Union and the MAHs disagree with the prices suggested by EOF, EOF will only accept verifiable supporting documents, such as websites of member-states where the price of the products, the nature of the price (ex-factory, wholesaler, retail) will be verified, the official reducing factors and the date the relevant prices will apply, original letters

of the official competent authorities of the member-states, officially translated by the Ministry of foreign affairs or an attorney-at-law, which will record the above data for the prices. No supporting documents can be accepted, when deriving from websites with subscription, sales invoices or letters of MAHs. In case the reference medicinal product has a different package in these reference countries, reduction is made in accordance with the provisions of article 9.

5. No prices will be issued for medicinal products which, although approved, no sales thereof were realised in the past three years from the date the procedure for the issue of prices commenced or have no sales for three consecutive years after the issue of their marketing authorisation, regardless if the marketing authorisation has not been revoked by EOF's verifying act. For these medicinal products, if their marketing authorisation has not been revoked and they fall into the cases of par. 6 of article 40 of the above Joint Ministerial Decision ΔΥΓ3α/Γ.Π.32221/ 2013, a supplementary prices bulletin can be issued, upon the companies' request. Following a request, which is filed to the competent service, the marketing authorisation holder may request a lower price with no restrictions, which is directly approved in a supplementary/corrective prices bulletin.

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

1. The maximum producer's price (ex-factory) of the reference medicinal products after the expiration of the patent protection 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 recorded by EOPYY sales have been realised in the market, during the past twelve months before the commencement of the re-pricing by EOF (unique medicinal products), the average of the three lower prices in the EU member-states exclusively applies. When a generic is sold in the market and sales thereof are realised, the 50% reduction applies even if it is lower than the average of the three lower prices in the EU member-states. No increase of prices of the existing medicinal products is permitted save in the case of corrections of preceding errors.

2. For the products for which the patent protection of active substance 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 further 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 which the patent protection of active substance expired before 01.01.2012, flat reductions of prices apply, as defined in a Ministerial Decision, each time a Prices Bulletin is published. In particular, 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

8% 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 4% and the prices of the products with a price lower than €5.99 are not reduced. In case the flat 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 by EOF or during the evaluation of the prices by the prices committee that the average of the three lower prices in the EU member-states be obligatorily applied. The specific corrections may be incorporated to the supplementary bulletin. The flat reductions of the prices of medicinal products with a price marginally above the aforementioned limits of €6.00 and €12.00, may reduce their prices up to the said limits until these limits and in the next pricing thereof, the occasional flat reductions that apply to their category are enforced. The prices of medicinal products which may have been voluntarily reduced upon or after the issue of a prices bulletin are subjected – in the next prices bulletin – to flat reductions, only by the percentage that corresponds to any transgression of the already voluntary reduction offered, from the flat reduction as it applies on the original price, before the voluntary reduction. The MAH may apply the above either to EOF or to the Prices Committee. In co-marketing cases, any voluntary reductions of one of the trade names do not drag along the other trade name. Voluntary reductions of the prices of the medicinal products set out in this article do not automatically reduce the prices of generics, which are reduced only upon the request of the MAH.

Article 8:
Pricing of generics

1. The maximum price of the producer (ex-factory) or importer-marketing authorisation holder of generics is set to 65% of the price of the respective reference medicinal products, whose price is determined in accordance with the provisions of article 7 above. In case the reference medicinal product has a different package, then conversion is effected or in accordance with the provisions hereof. 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. More specifically, the price, if there are at least three reference medicinal products, is set to 65% of the average of the average of the three lower prices in the EU Countries. If no price of the reference medicinal product can be found in three countries, the determination of the price may be calculated by the price of even one medicinal product in a EU country.
In the cases of pricing of new generics, the provisions of this Decision apply. Especially for the new generics with marketing authorisation before 1/1/2012, the determination of their price will be based on the priced concluded by the reduction to the already priced generics before 1/1/2012 with the same or adjacent strength and package. No increase of prices of the existing medicinal products is permitted save in the case of corrections of preceding errors.
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. The reductions of the prices of medicinal products with a price that exceeds the above limits of Euro 6 and 12, do not exceed the said limits

3. In addition, for the generics of the preceding paragraph, dynamic pricing applies. More specifically, for each €250.000 sales that correspond to wholesale 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% to 15%. 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. On the first application of this Decision, the sales data of the last six months before the commencement date of the current re-pricing 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, flat price reductions apply, as specified by 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 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 4% 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 2% and the prices of the products with a price lower than €5.99 are not reduced. The flat reductions of prices of medicinal products with a price marginally above the aforementioned limits of €6.00 and €12.00, may reduce their prices up to the said limits and in the next pricing thereof, the occasional flat reductions that apply to their category are enforced. The occasional flat reductions of this paragraph may not reduce the price of a generic lower than 65% of the price of the reference medicinal product, save the relevant request of the marketing authorisation holder.

5. Moreover, for generics with a price exceeding Euro 12 in accordance with the provisions of the preceding paragraph, 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. 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. Following a request, which is filed to the competent service, the marketing authorization holder may

request a lower price with no restrictions, which is directly approved in a supplementary/corrective prices bulletin.

Article 9
Pricing of Special Case Medicinal Products

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 change or addition of a new pack size or strength of a medicinal product or an addition of a new similar form with the same administration channel, the determination of the price shall involve a correlation with the prices determined in accordance with the provisions of this Ministerial Decision and the following price is selected. The conversion is effected 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

2. 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. For different strengths that have been approved following complete documentation and in order to be authorised by EOF and marketed in at least 3 EU countries, EOF may suggest its exemption from the above reductions. A condition for the proportionate calculation of the prices is that both correlated

products concern individual dosages. In case of individual dosages, where the correlation is proportionally performed, the case of transcutaneous plaster is included.

Article 10:
Medicinal products produced in Greece

1. Medicinal products exclusively produced in Greece which cannot exactly correspond as to the pharmaco-technical form or content to reference medicinal products authorised in the domestic pharmaceutical market, as well as medicinal products under a Greek patent, are characterised as "domestically produced" and 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, as well as 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 sale 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 investments, 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 amortizations, interest and third-party profits (contract manufacturing).

5. Until the issue of the prices bulletin of January 2015, EOF will collect the necessary data for the preparation of an updated list with the specific medicinal products and for the calculation of the prices, in accordance with the provisions hereof. On the first application of this decision and thereafter, a flat price reduction is applied on these medicinal products. This reduction amounts to 0% for products with a retail price less than Euro 5.99, 1% for products with a retail price ranging from Euro 6.00 to 11.99 and 2% for products with a retail price above Euro 12.00. The medicinal products subjected to the provisions of this article cannot have a retail price that exceeds the one of the respective reference medicinal products. EOF may propose during the filing of the prices to the competent committee of the Ministry of Health, any criterion that contributes to the due application thereof in relation to the relevant, as well as other provisions of this decision.

Article 11
Obligations of pharmaceutical companies

1. After the end of each accounting period, pharmaceutical companies shall be required to file to the Directorate of Medicinal Products and Pharmacies and the Directorate of Prices of Medicinal Products, the following data: Within a deadline of one month, volume and value data on their sales during the management period under review, within a deadline of four months, the balance sheet and expenditure statement (detailed and in summary form). Filing 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 which will be required to provide access thereto, to all the accounting books and records it keeps. 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 certified 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 medicinal products equal to three (3) months' supply per product code, based on the sales of the preceding year.

Article 12
Filing of supporting documents and deadlines for pricing

1. For the purposes 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 filed at the competent Service or emailed to price_list@eof.gr, communicated in parallel to the Directorate of

Medicinal Products and Pharmacies of the Ministry of Health, as well as to the e-mail address farmaka.times@yyka.gov.gr.

2. For all medicinal products of foreign origin (manufactured, packed, imported), a certificate by the foreign company, authenticated by the relevant authorities, must be filed 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, whereas for generics in 30 days. 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 request the matter to be re-examined. 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 deadline may be extended for more days. In the case of an application for an increase in the price, the provisions of the respective articles hereof shall apply. The applicant must prove the changes that have occurred and 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 its medicinal products from the Price Bulletin, provided that it files a certificate proving that it has 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 medicinal products 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 and emailed to: price_list@eof.gr, communicated in parallel to the Directorate of Medicinal Products and Pharmacies of the Ministry of Health, as well as to the mail address farmaka.times@yyka.gov.gr. Furthermore, a Solemn Declaration under Law 1599/86 shall be filed, stating the price of purchase from the supplier with an official sale invoice for the imported quantity attached thereto.

Article 13
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 carrying medicinal products to the facilities of country (regional) wholesalers and pharmacies shall be borne by manufacturers or importers. Such costs shall be borne by wholesalers with respect to products sold to country pharmacies. Exceptionally, wholesalers shall bear no transport costs for orders not exceeding 10 Euros in value.

5. In the event a price freeze of medicinal products or of certain categories of medicinal products is imposed, 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 relevant decision is fully justified and announced to the applicant within 90 days.

7. Manufacturers, packers and importers of medicinal products shall be required to withhold a contribution in favour of the Hellenic Association of Pharmacists (0.4‰ of the wholesale price) for their sales to wholesale drugstores and pharmacies. The contribution shall be collected and reimbursed to the Hellenic Association of Pharmacists through the Pension Fund for Health Professionals (TSAY). Wholesale drugstores shall respectively withhold the contribution from pharmacists. For medicinal products exported by wholesale drugstores, the proportion of the contribution corresponding to exports (which has already been withheld by pharmaceutical companies) shall be returned to wholesale drugstores with the same procedure as in the case of other contributions 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 Hellenic Association of Pharmacists 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 5th month from the end of the six-month period to which they relate. More specifically, for the exports realised within the first six-month 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 performed within six (6) months from the date the request and the lawful supporting documents were timely filed.

Article 14
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 Decision No 49515/06-06-2014 (gov. Gazette B 1530) is abolished.

This Decision must be published in the Government Gazette.

Athens, July 11, 2014

THE MINISTER

MAVROUDIS VORIDIS