GOVERNMENT GAZETTE
OF THE HELLENIC REPUBLIC

SECOND ISSUE Sheet No 1958
September 11, 2015

DECISIONS

No Γ5(a)/οικ.69976

Provisions on the pricing of medicinal products

THE MINISTER OF HEALTH

Having considered:
1. 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).
2. The provisions of article 13 of Law 3408/2005, as amended and in force (Gov. Gazette A' 272).
3. The provisions of article 14, par. 3 of Law 3840/2010 (Gov. Gazette A' 53) as amended and in force.
4. The provisions of Law 3842/2010 (Gov. Gazette A' 58) as amended and in force.
5. The provisions of article 4 par. 2 of Law 3899/2010 (Gov. Gazette A' 212), for the amendment of VAT Code.
6. The provisions of Law 3918/2011 (Gov. Gazette A' 31) "Structural changes in the health system and other provisions" as amended and in force.
7. 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.
8. The provisions of article 12 of law 3816/2010 (A' 6), as supplemented with par. 5 of article 63 of Law 3918/2011 (A' 31) and the provisions of article 40 and article 51 of law 3918/2011 (A' 31).
9. The provisions of article 22 of Law 4213/2013 (Gov. Gazette A' 261) as amended and in force.
10. The provisions of article 34 of Law 4025/2011 (Gov. Gazette A' 228).
11. The provisions of article 27 of Law 4320/2015 (Gov. Gazette A' 29).
12. The provisions of article 2, par. (F) of Law 4336/17-08-2015 (Gov. Gazette A' 94).
13. The provisions of article 17 of the l.d. 96/1973 (Gov. Gazette A' 172), as amended and in force.
14. The l.d. 136/1946 "for the Market Police Code" (Gov. Gazette A' 298), as amended and in force.
15. The provisions of article 90 of the P.D. 63/2005 "Codification of legislation for the Government and Government Bodies" (Gov. Gazette A' 98).
16. The provisions of the P.D. 106/2014 (Gov. Gazette A' 173) "Organisation of the Ministry of Health and Welfare" as amended and in force.
17. The P.D. 65/2015 (Gov. Gazette 106/A'/28-08-2015) "Appointment of Ministers, Alternate Ministers and Deputy Ministers".

18. 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.
19. 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).
20. The Ministerial Decision No ΔΥΓ3(α)/οικ.94274/28.9.2012 "Application of article 15 in Law 4052/2012" (Gov. Gazette B' 2675).
21. The Order of the Minister of Health dated 9/9/2015 which was forwarded to us by e-mail, to which a draft Decision was attached.
20. The fact that no expenditure is incurred against the State Budget from this decision, according to the Recommendation under Number 65556/27-08-2015 of the Directorate of Budget and Fiscal Reporting, we decide:

WE DECIDE

Article 1:
Definitions and Categories of Priced Medicinal Products

1. Reference medicinal product is any 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 pricing method of the medicinal products is different after the documented expiration of the ten-year or possible eleven-year on-patent period provided for by article 11, par. 1 of the Joint Ministerial Decision No ΔΥΓ3α/Γ.Π.32221/2013 (Gov. Gazette B 1049) 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 aforementioned definition is exclusively and only used for pricing purposes and cannot be used by third parties for any other purposes.

2. Generic is any 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 solid pharmaco-technical forms administered Per Os with direct release are deemed as one and the same pharmaco-technical form. For the pricing purposes, the cases of article 12 of the Joint Ministerial Decision (KYA) No ΔΥΓ3α/Γ.Π.32221/2013 (Gov. Gazette 1049/B'/29.4.2013) are also subjected to the provisions on the pricing of generics. For the case of the pricing of medicinal products, which obtain a marketing authorisation 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 (original) reference product. Hybrids approved in accordance with 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 lowest 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 literature medicinal products are priced in the same manner as the hybrids.

3. The characterisation of a medicinal product as a reference medicinal product under protection (on-patent) or as a reference product under no protection (off-patent), as a generic, as a hybrid, as a biological medicinal product, orphan or literature medicinal product or as a fixed combination of medicinal products is made by EOF, using the same legal basis according to which the marketing authorisation for the medicinal product is granted, who grants its opinion and recommends the pricing of specific cases. 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 net 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 (ex-factory) price is based on the wholesale price reduced (a) for all medicinal products whose cost is reimbursed by the Social Insurance Agencies with a price of 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 medicinal products (OTC) by 7.24%.

2. The 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 a 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. The 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 of the pharmacy, as specified in par. 2-4 of article 3 hereof and the applicable Value Added Tax (VAT).

4. The 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, the 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 provided that they operate a hospital pharmacy. The maximum hospital price shall be determined on the basis of the ex-factory price reduced by 8.74%.

5. 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 Health Products of the Ministry, to whom the request is filed. The Marketing Authorisation Holder is entitled to file an application for the removal of a medicinal product from the Prices Bulletin, if the marketing thereof has previously lawfully ceased.
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 manufacturing 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 drug traders, the gross profit margin (mark-up) shall be determined as follows: a) for non-prescription medicinal products (OTC), as a percentage of up to 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 net 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 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 €3,000, a mark-up of 2% is 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 if they operate a hospital pharmacy, 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 wholesalers, pharmacies and co-operatives, provided that any such discount is recorded on the sale invoice.

In cases of direct sales to pharmacies, the discount on the wholesale price also includes the gross profit margin of the wholesalers, which is reimbursed to EOPYY in accordance with the provisions of the Ministerial Decision Γ5/οικ.30468 (Gov. Gazette 869/B'/19-5-2015).

3. Wholesalers may grant a discount of up to 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 on the maximum price, provided that any such discount is recorded on the sale invoice.

4. MAHs are obliged to grant to pharmacies, wholesalers 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 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 Police 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 Health Products of the Ministry of Health in order for its lawfulness to be examined and for approval. All data sources, dates, assumptions, conversions, factors and exchange rates, as well as any relevant information applied to the calculation of prices are each time posted at EOF's website. Price 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 of the Ministry of Health. 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. The Directorate of Medicinal Products and Health Products of the Ministry of Health, issues the occasionally updated list with hospital prices to be used by services and agencies of the Public Sector.

2. According to the law, prices of all medicinal products are revised twice per year and the price 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 filing of the application within the timeframe set out in the Transparency Directive, as this has been transposed into the National Law. Specifically, in the case of generics, prices are published within 30 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 price bulletins will be issued, according to which, all new generics for which an application was filed 30 days before the procedure for 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 procedure of 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

uninterrupted access of patients to new medicinal products, a prices bulletin of new medicinal products which has been duly prepared by EOF at a preceding time, may be issued in parallel with the general prices bulletin, although the ex-factory prices and the exchange rates have been calculated with delay.

3. When calculating the final prices of new medicinal products to be priced, countries may be used in which a product was sold, until the date the prices were evaluated by the competent Pricing Department of EOF and not strictly on the date the procedure was initiated by EOF. 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 set out in par. 2 of article 12 of Law 3816/2010. The maximum ex-factory price for the OTC medicinal products as well as for the products included in the negative 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 pricing thereof, as a product of 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. In this case, other data apart from those set out in article 6 and/or solemn declarations of the MAHs may be considered reliable. 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. Any remarks are filed within three (3) business days to EOF, who then consults for five (5) days and then makes its final suggestion to the Minister of Health and to the competent Directorate of the Ministry and publishes it. The prices of medicinal products included in the negative list and the list of OTC medicinal products are not re-priced. The retail prices of the medicinal products which, by virtue of the decision of the competent bodies, shift from the positive or negative list of prescribed medicinal products of article 12 of Law 3816/2010 to the list of OTC medicinal products are not altered.

4. Objections on the published prices, if they have been filed within five (5) days, are all answered by the competent department of the Directorate of Medicinal Products and Pharmacies of the Ministry of Health 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. Increases are allowed and accepted in case of corrections of errors which (corrections) are included in the supplementary prices bulletin issued within thirty (3) days 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 to 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 issued, 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 in 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 Joint Ministerial Decision (ΚΥΑ) ΔΥΓ3α/Γ.Π.32221/2013 (Gov. Gazette 1049/B'/29.4.2013) and evaluated by the competent department of EOF as new requests for pricing. Consequently, the MAHs must file all necessary supporting documents accompanying the new requests, including the relevant surety bonds.

6. In exceptional and specific 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. For the parenteric solutions that concern only serums-electrolytes, uniform prices are determined, based on the active substances, strength (content), packages and other cost elements. 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 lowest 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 lowest 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 and vaccines are excluded from re-pricing. Orphan medicinal products may be priced even if prices are available in only two other EU countries. 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 lowest 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 lowest prices of the EU for the same medicinal product, re active substance, pharmaco-technical form, strength and packaging (nine-digit Code of EOF) in the member-states of the European Union which publish reliable data. In case the same medicinal product does not exist in three countries, it will not be priced. No price increases of existing medicinal products is permitted but 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 or to official or reputable European Agencies. Access to the said sources for the collection of data is granted via designated websites of the official sources of each EU member-state and/or via the official and reputable agencies such as the EURIPID. During the investigation, any price available is sought (ex-factory, wholesale, retail). Special emphasis must be given 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. The exchange rate applied, 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 of medicinal products include: 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 or via another electronic procedure, with the technical specifications each time announced through EOF's website.

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 all respective information in the Data and Prices Research Sheets, which have been designed for the purposes of concentrating 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.

4. Filing of requests, sheets, queries, data as well as any other communication of pharmaceutical companies with the Department of Prices of Medicinal Products of EOF is also possible via the e-mail address announced by EOF. 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 lowest prices and the MAHs disagree with the prices suggested by EOF, EOF will only accept verifiable supporting documents, such as official websites of member-states where the price of the products will be confirmed, the nature of the price (ex-factory, wholesaler, retail), 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 subscribers' websites, sales invoices or letters of MAHs.

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 first pricing, 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 scope of 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 MAHs request. Following a request, which is filed to the Directorate of Medicinal Products and Health Products of the Ministry of Health, the Marketing Authorisation Holder may request a lower price without any restriction, which is directly approved in a supplementary/corrective prices bulletin by the same Service.

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 data protection period, which was determined in article 1 above and the first marketing (documented with the existence of the first invoice issued) of a respective generic in the Greek market, is automatically to 50% of the latest price under protection. For reference medicinal products with no generic or only with similar medicinal products priced in accordance with article 10 hereof, with sales that have been recorded by EOPYY for reimbursed products and by EOF for non-reimbursed products, during the last twelve months before the date the re-pricing process commences by EOF, the average of the three lowest prices in the EU member-states applies.

2. Following a request which is filed to the Directorate of Medicinal Products and Health Products of the Ministry of Health, the Marketing Authorisation Holder may request a lower price, without any restriction, which is directly approved in a supplementary price bulletin which is issued by the same Service. 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. For the purposes of promoting the use of cheaper treatments and protecting the Public Health and in order not to endanger the adequacy of the said products to cover patient's needs, the reductions set out in par. 1 of this article apply to medicinal products with a Daily Treatment Cost greater than €0.40 or a retail price over €12 and up to that level.

Article 8:
Pricing of generics

1. The maximum price of the producer (ex-factory) or importer MAH of generics is set to 32.5% of the price of the respective reference medicinal products under protection. In case generic packaging exceeds monthly treatment needs and differs from the package of the reference medicinal product, then a reduction is effected in accordance with the provisions of article 9 hereof and the lowest price will be taken into account. In addition, if there is no reference medicinal product for the generic in the Greek market or the EU market, the price of the generic is calculated based on the price of another generic. If there is no reference medicinal product and there is no other generic, then the price is calculated based on the lowest price of the active substance and similar pharmaco-technical form. For the domestically produced generics for which no reference medicinal product or another generic exists, the pricing procedure set out in article 10 hereof is followed (determination of the price based on the cost).

2. Following a request which is filed to the Directorate of Medicinal Products and Health Products of the Ministry of Health, the Marketing Authorisation Holder may request a lower price, with no restrictions, which is directly approved in a supplementary prices bulletin which is issued by the same Service.

3. For the purposes of promoting the use of cheaper treatments and protecting Public Health and in order not to endanger the adequacy of the said products to cover patients' needs, the reductions set out in par. 1 of this article apply to medicinal products with a retail price over €7.8 as well as to medicinal products with a Daily Treatment Cost exceeding €0.26 and up to that level.

4. In addition, for generics set out in this article with a retail price exceeding €12, dynamic pricing is implemented. More specifically, for each increase in sales of €250,000 which correspond to wholesale prices in the year preceding the publication of the prices bulletin, the prices determined as above are reduced, so that dynamic pricing is further effected by 1% to 15%. Dynamic pricing is applied for the first time after the completion of two calendar years from the date the generic was marketed for the first time and it is conducted once a year, during the first revision of the prices set for each year. The sales are assessed based on the sales data received by EOPYY, for the 12-months period preceding the issue of each price bulletin. The reduction of prices that result from the dynamic pricing, are off-set against other reductions in prices, applied to generics.

Article 9
Pricing of Special-Case Medicinal Products

1. In case the manufacturer of a medicinal product or the packager or both change, the price that the said product had before the change is deemed as the maximum limit.
2. All packages that cover up to monthly treatment are priced proportionately with the respective measurement unit of the specific pharmaco-technical form. The same regulation applies in the case of new similar form with the same route of administration.

3. In case of larger packages, in order for their price to be determined a correlation with the prices of the most approximate package, determined in accordance with the above-mentioned articles of this Ministerial Decision, is performed. The conversion is effected as follows:
a) From a smaller to a larger package/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 package size/strength, the price is calculated on the standard package.

4. The forms of one-dosage injected medicinal products, sachets and ocular solutions in single dosage are excluded, which are proportionally calculated.

Article 10:
Medicinal products produced in Greece

1. Medicinal products exclusively produced in Greece which cannot exactly correspond, as to their pharmaco-technical form or content, to reference medicinal products marketed 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) expenses for 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 cost of raw materials 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. For the medicinal products involving research on active substance or pharmaco-technical form for a Greek patent and for which there are clinical pharmacokinetics

trials and a marketing authorisation by EOF, the cost configuration process shall additionally take into account the value of new investments, the cost of research and development of the active substance or pharmaco-technical 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).

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 Health Products, the following data: Within a deadline of one month, volume and value data on their sales during the accounting period in question, within a deadline of four months, the balance sheet and expenditure statements (detailed and in a consolidated form). Filing of the aforementioned data shall be a prerequisite for the consideration of any request for the approval and/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 employees of Ministry of Health at the registered office of the company which will be required to grant to them, access 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 manufacturing or importing other goods apart from medicinal products, must 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 are obligated to keep a 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 product. Moreover, the quantities produced and their value at ex-factory prices shall be recorded in the said book. 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 Police Code).

6. Pharmaceutical companies are obligated to ensure the availability of stock 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 (EMA), the MAH may request the determination of their price, for which the relevant application shall be required. The said applications shall be filed to the Pricing Department or EOF or e-mailed to the e-mail address communicated each time by the said Service, communicated in parallel to the Directorate of Medicinal Products and Health Products of the Ministry of Health, as well as to the e-mail address communicated each time by the said Service.

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 Pricing Department of EOF, 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 Pricing Department of EOF suggests the issue of the relevant Price Bulletin within 90 days the date the application was filed, whereas for generics in 30 days. If the data accompanying the application is inadequate, then the above deadline commences from the date the applicant will file all data provided for. 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 a price increase, 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 further 90 days.

5. A Marketing Authorisation Holder may request the removal of its medicinal products from the Price Bulletin, provided that it files a certificate proving that it has given to EOF a three (3) 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, the filing of a relevant application shall be required. Such applications shall be filed to the competent Service and e-mailed to the e-mail communicated each time by the said Service, communicated in parallel to the Directorate of Medicinal Products and Health Products of the Ministry of Health, as well as to the e-mail address communicated each time by the said Service. 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 (EMA). Hospital (large-size) packages may not be sold in parts by pharmacies.

2. Medicinal products designated by their marketing authorisation as intended "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 sale price. For the OTC medicinal products, the indicated retail price is suggestive and constitutes the maximum retail price until 01-01-2016.

4. The costs for the transportation of medicinal products to the registered office of country (regional) wholesale drugstores and pharmacies shall be borne by industrial companies or importers. Such cost shall be borne by the 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 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 a sufficient description of these reasons. The relevant decision is fully justified and announced to the applicant within 90 days.

6. 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 in favour of the Hellenic Association of Pharmacists 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 be exclusively borne by the purchasing pharmacists who operate a pharmacy 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 reimbursement of the exports VAT, based on the law in force from time to time. The requests for the reimbursement of the amount with the necessary supporting documents from the wholesale drugstores 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 each 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.

7. The sale prices of medicinal products that apply before the above re-pricing continue to apply for a period of thirty (30) days for wholesalers and co-operatives and forty-five (45) days for pharmacies.

Article 14
Authenticity sticker or barcode of medicinal products

1. 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.

Any prior relevant decision is annulled and has no effect from the date this Decision enters into force.

This Decision must be published in the Government Gazette.

Athens, September 9, 2015

THE MINISTER

MELETIOS – ATHANASSIOS DEMOPOULOS