

## **MINISTERIAL DECISION 325/5851/Γ.Π.**

### **Provisions on the pricing of medicinal products**

THE MINISTER OF HEALTH

Having considered: (...)

### **WE DECIDE**

#### **Article 1:**

#### **Definitions of Priced Medicinal Products**

1. Reference medicinal product is a medicinal product which is approved by virtue of article 11, par. 2(a) of the Joint Ministerial Decision (KYA) No ΔΥΓ3α/Γ.Π.32221/2013 (Gov. Gazette 1049/B/29.4.2013), according to the provisions of article 9 thereof. Exclusively and only for pricing purposes, a medicinal product is no longer protected (off-patent) after the documentation that the protection period of its active substance has expired, either in Greece or in other countries of the EU. In case no reliable data exist, in relation to the expiration of the patent of the active substance, as an alternative, the expiration of the ten-year or possible eleven-year patent period provided for by article 11, par. 1 of the Joint Ministerial Decision No ΔΥΓ3α/Γ.Π.32221/2013 (Gov. Gazette B 1049) applies, and respectively the six-year protection period for the medicinal products that obtained a marketing authorisation before the Joint Ministerial Decision No ΔΥΓ3α/83657/2006 (Gov. Gazette B 59/24.1.2006) entered into force. The on-patent period for the active substance supersedes the protection period if the former ends at a posterior time. Generic is a medicinal product, as defined in article 11, par. 2(b) of the above Joint Ministerial Decision, with the same quantitative and qualitative composition in terms of active substances, the same pharmaco-technical form with the reference medicinal product whose bioequivalence with the reference medicinal product has been proven, based on the appropriate bioavailability studies. Various salts, esters, ethers, isomers, isomer mixtures, complexes or derivatives of an active substance are considered to be one and the same substance, unless their properties differ substantially, in terms of safety and/or efficacy. Various pharmaco-technical forms administered Per Os with direct release are deemed as the same pharmaco-technical form. The characterisation of a medicinal product as a reference medicinal product,

as under or no protection, or as generic is made by EOF, who delivers opinion and recommends for pricing of special cease of pharmacotechnical forms.

## **Article 2: Prices of Medicinal Products**

1. The maximum producer's or importer's price (ex-factory) is the sale price from the marketing authorisation holders (MAHs) and the importers, manufacturers, packagers and distributors deemed equal therewith, to the wholesalers and is calculated in accordance with the provisions hereof. The producer's price is based on the wholesale price reduced (a) for prescribed medicines which are not reimbursed by the Social Insurance Agencies by 5.12% and (b) for those whose cost is reimbursed by the Social Insurance Agencies by 4.67%.
2. Maximum Wholesale Price of Medicinal Products is the price at which medicinal products are sold to pharmacies. This price includes the gross profit margin of the holder of the license for the wholesale of medicinal products, which is calculated as a percentage on the maximum price of the Marketing Authorisation Holder.
3. Maximum Retail Price of Medicinal Products is the price at which medicinal products are sold by pharmacies to consumers, and it is defined by the wholesale price, adding the lawful profit margin of the pharmacy and the applicable VAT.
4. Maximum Hospital Price of Medicinal Products is the price at which medicinal products are sold by the Marketing Authorisation Holders to the State, public hospitals, Social Care Units, EOPYY pharmacies of EOPYY and the public law legal entities referred to in par. 1 of Article 37 of Law 3918/2011, pharmacies of private clinics with over 60 beds and the relevant pharmacies and wholesale drugstores for the medicinal products of par. 2 of Article 12 of Law 3816/2010. The maximum hospital price shall be determined on the basis of the maximum producer's price, with the exception of the first application hereof, where the maximum hospital price is determined based on the maximum wholesale price reduced by 13%.
5. Especially for medicinal products within the scope of par. 2 of Article 12 of Law 3816/2010, a special method for the calculation and determination of the wholesale and retail prices shall apply as follows: a) a wholesale profit margin of 2% shall be added to the hospital price in

order to obtain the Special Wholesale Price. On the resulting price, a fixed amount of €30.0 shall be added as profit margin of the private pharmacy to obtain the retail price. The VAT shall be added to the final price.

6. For the needs of pricing, the provisions for pricing of generics also includes the case of par. 3 of article 11 of the Joint Ministerial Decision (KYA) No ΔΥΤ3α/Γ.Π.32221/2013 (Gov. Gazette 1049/B/29.4.2013), as well as the cases of article 12. For the case of the pricing of medicinal products, which obtain license by virtue of article 14 of the above KYA, the “reference product” preserves its price until the end of the 10-year data protection period and the second (and any subsequent product) is priced in accordance with the “reference product” within the period before the expiration of the 10-year data protection period of the (initial) “reference product”.

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

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

### **Article 3: Profit margins**

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

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

#### **Article 4: Discounts and Credit**

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

2. Manufacturers, packers and importers may, without any quantitative restrictions, offer a discount on the wholesale price for the non-prescribed (OTC) medicinal products, as well as for the medicinal products referred to in par. 2 of Article 12 of Law 3816/2010. For all other products, manufacturers, packers and importers may offer a discount of up to 10% to wholesalers, pharmacies and cooperatives, provided that the amount of the discount is indicated in the sale invoice.

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

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

5. For the pharmacies of private clinics with over 60 beds, the additional discount under paragraph 1 shall be applied on the hospital price. As a

requirement, such additional discount shall be indicated on the sale invoice or will be concluded by a written agreement between the two parties.

6. The discovery of the transgression of the discount limit or of the non-compliance with the requirements of paragraph 2 of this article shall incur, further to the sanctions provided for in the Market Control Code, an immediate reduction of the price of the medicinal product concerned in an amount proportionate to the additional discount offered.

7. In case the MAHs effect direct sales to the pharmacies, they return to EOPYY the wholesale profit that has been incorporated in the price of the medicinal products as the profit of the wholesalers. The said return is effected with the filing of statements of sales to EOPYY which will declare the value of their direct sales to the pharmacies, where the sales effected to the pharmacies and the wholesaler profit corresponding thereto will be depicted in an analytical and consolidated manner. Respective data are also requested by EOPYY from the pharmacies. The calculation of the wholesale profit will be effected in accordance with the provisions of article 3 of this Ministerial Decision. EOPYY adopts all measures necessary for the application of this paragraph

## **Article 5: Procedural and administrative issues**

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

2. According to the law, the prices of all medicinal products are revised twice per year and the prices bulletins are issued, in January and July respectively, of each year. Additional prices bulletins may be issued once

the above dates elapse for the pricing of new medicinal products. For the purposes of smooth organising and operation of the market and for the continuous access of patients, a prices bulletin of new medicinal products which has been duly prepared by EOF at an preceding time, may be issued in parallel with the general prices bulletin, although the producer's prices and the exchange rates have been calculated at a later stage. Before their filing to the Minister of Health, EOF sends the concluded, based on the data available to it, prices, to each MAH separately for any comments. For generics, the reference price from which the price of the 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 publishes it.

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

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

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

remain unchanged. However, 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 or importer's price (ex-factory) of all biological products (blood products, biotechnological products, vaccines, bio-similar products and other biological products) is set as the average of the three lower prices in the EU countries. Exceptionally for blood derivatives, the resulting prices cannot be less than the average of the three lower prices of the 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. Medicinal products which, by decision of the Positive List Committee are shifted from the positive to the negative list or to the list of OTC medicinal products or vice versa, are priced, before their shift, first in accordance with the provisions in force from time to time that correspond to the medicinal products of the category in which they are reclassified. The prices of medicinal products which, upon the MAH's request, are shifted from the positive to the negative list of prescription medicinal products and their cost is not reimbursed, are determined based on the price of the average of the three lower prices of the respective products of the EU Countries. If they are re-included upon the MAH's request in the positive list of prescription medicines, the occasionally applicable provisions hereof apply.

6. In case the Reference Medicinal Product of a generic, has a different package or strength, then reduction of the package or strength is effected, in accordance with the provisions of this article 9. A respective reduction is also effected in case the original has a price in another form or other strength in the reference country.

#### **Article 6:**

#### **Pricing of reference medicinal products under protection (on-patent)**



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

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

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

4. EOF is also able to examine, apart from the data independently collected by its competent department, the data provided by the Marketing Authorisation Holders which is filed in the form of a statement with the respective information in the Data and Prices Research Sheets,



which have been designed for the purposes of gathering all data required for the invoicing of the reference medicinal products. Data and Prices Research Sheet of Medicinal Products is filled in, signed and filed in the above manner, via EOF's portal, by the MAH of each medicinal product and serves as a solemn declaration, thus entailing all legal liabilities and sanctions provided for by the laws in case of false statements. In addition, in case erroneous data is filed or data is concealed, sanctions may also be imposed by the Minister of Health, in accordance with article 69 of law 3984/2011, following the granting of opinion by the Prices Committee. Filing of requests, sheets, queries, data as well as any other communication of the pharmaceutical companies with the Department of Medicines Prices of EOF is also possible via the email [newdrugs042013@eof.gr](mailto:newdrugs042013@eof.gr).

5. No prices will be issued for medicinal products which, although approved, did not show any sales in the last three years from the issue of the list or have shown 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 ΔΥΤ3α/Τ.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.

6. Orphan medicinal products may be priced even if prices are offered in only two other European countries. The maximum producer's or importer's price (ex-factory) 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 less or equal with the applicable ones.

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

1. The maximum producer's or importer's price (ex-factory) of the reference medicinal products after the expiration of the patent of the active substance, which was determined in article 1 above, is automatically reduced either to 50% of the last under protection price or to the average of the three lower prices of the EU member-states, keeping the lowest between the said two prices. More specifically, for medicinal products with no generic for which sales have been realised in the market (unique medicinal products) the average of the three lower prices in the EU member-states applies. When a generic is sold in the market, the 50% reduction applies even if it is lower than the average of the three lower prices in the EU member-states. During the initial application of this decision, no increase of prices is permitted in the case of existing unique medicinal products where average of the three lower prices is higher than the existing price.

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

3. For the products for whose the patent protection of active substance expired before 01.01.2012, horizontal reductions of prices apply, as defined in a Ministerial Decision, each time a Prices Bulletin is published. More specifically, for the first Prices Bulletin to be issued after the publication of this decision, the prices of all medicinal products prior to 01.01.2012 with an existing retail price of over Euro 12 per package are reduced by 10% on the wholesale price. Similarly, the prices of all products set out in the above paragraphs with an existing retail price ranging among €6.00 to €11.99, are reduced by 5% and the prices of the products with a price lower than €5.99 are reduced by 2.5%. In case the horizontal or other reduction of prices to be applied, reduce the price of a unique product below the average of the three lower prices in the EU member-states the MAH may request from the prices committee of EOF that the average of the three lower prices in the EU member-states be applied. The specific corrections may be sent to the competent committee of the Ministry of Health with a supplementary bulletin. The horizontal reductions of the prices of medicinal products with a price marginally

above the aforementioned limits of €6.00 and €12.00 as well as the application of paragraph 1 on medicinal products whose patent protection expired after 01.01.2012, may not reduce their prices below the said limits, for one any only re-pricing. In the next re-pricing, the horizontal reduction provided for the category in which it has been included with the preceding reduction of prices, applies. ~~The Ministerial Decision, which will have the force of a market police regulation, will regulate the remaining details for the application of this article.~~

## **Article 8: Pricing of generics**

1. The maximum price of the producer or importer-marketing authorisation holder (ex-factory) of generics is set to 65% of the price of the respective off-patent medicinal products, whose price is determined in accordance with the provisions of article 7 above. In case the reference medicinal product has a different strength or package, then an approximate conversion from a similar reference product is effected or in accordance with the provisions of paragraph 6 of article 5. Moreover, if no reference medicinal product exists for a generic in the Greek market, the price of the generic is calculated based on the application of the preceding provisions in articles 6 and 7 for the calculation of the reference price ~~and then reduction is effected based on the provisions hereof.~~

2. This regulation applies to all products that will obtain a marketing authorisation from the date this decision will be published, for generics which obtained a marketing authorisation from 01.01.2012 and after, and for all generics corresponding to active substances whose patent protection is no longer in force from 01.01.2012 and forth.

The new packages, forms and strengths of generics whose initial product marketing authorisation had been issued before 01.01.2012 are subject to the same pricing provisions with the generics that obtained a licence before the said date. The provisions of this paragraph for the prices of generics apply on the prices of the reference medicinal products that will result from the application of the provisions of article 7.

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

4. For all other generics which do not fall into the scope of the provisions of the preceding paragraphs, horizontal price reductions apply, as specified by a Ministerial Decision, each time a Prices Bulletin is issued. More specifically, for the first Prices Bulletin to be issued after the publication of this decision, the prices of all medicinal products not falling into the scope of the provisions of the preceding paragraph, with an existing retail price of over Euro 12 per package are horizontally reduced by 15% on the wholesale price. Similarly, the prices of all products set out herein, as well as in the above paragraphs with an existing retail price ranging among €6.00 to €11.99 are reduced by 5% and the prices of the products with a price lower than €5.99 are reduced by 2.5%. The horizontal reductions of prices of medicinal products with a price marginally above the aforementioned limits of €6.00 and €12.00, may not reduce their prices below the said limits, for one any only re-pricing. In the next re-pricing, the horizontal reduction provided for the lower category in which it has been included with the preceding reduction of prices applies. The occasional reductions 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 of the preceding paragraph with a price exceeding Euro 12, a system of dynamic pricing and retrospective application of rebates is implemented. More specifically, for each percentile increase unit of their penetration in the market, their price will be reduced by one percentile unit and the respective retrospective rebate will be imposed. The first application of the specific provision will take place in July 2014. More specifically, the sales in quantities of 2014 will be compared to the sales in quantities of 2013 regarding the cluster of the positive list in which the product has been classified so as to assess the market share thereof. If there is increase of sales and of the market share, then the price will be prospectively reduced in the future and a rebate will be retrospectively imposed on the producer's price, based on the resulting

new price. The sales are assessed based on the sales data available to EOPYY and EOF. 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**

### **Special case Medicinal Products Pricing**

1. In the event of a change of the manufacturer of a medicinal product or the packager or both, the price that the said product had before the change is deemed as the maximum limit.
2. In the event of a replacement or addition of a new pack size or strength of a medicinal product or an addition of a variation (provided that the variation refers to the same route of administration), the determination of the price shall involve a correlation with the prices determined in accordance with the provisions of the Ministerial Decision No 113429 (Gov. Gazette 3117/B/09-12-2013).
3. The conversion of packages and strengths shall take place as follows:
  - a) From a smaller to a larger pack/strength, the unit price shall diminish up to a maximum of 12%, as follows:

Increase in pack size (%)	Reduction of proportional price (%)
up to 5	1,67
from 5.01 to 10	3.18
from 10.01 to 15	4.56
from 15.01 to 20	5.83
from 20.01 to 25	7.00
from 25.01 to 30	8.08
from 30.01 to 35	9.07
from 35.01 to 40	10.00
from 40.01 to 45	10.86
from 45.01 to 50	11.67
from 50.01 to 60	12.00
over 60	On a case-by-case basis

- b) From a larger to a smaller pack size/strength, the unit price shall increase up to a maximum of 12%:

Reduction in pack size	Increase of proportional price
up to 5	1.32
from 5.01 to 10	2.78
from 10.01 to 15	4.41
from 15.01 to 20	6.25
from 20.01 to 25	8.33
from 25.01 to 30	10.71
from 30.01 and over	12.00

4. 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 lower 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.

#### **Article 10: On-patent medicinal products produced in Greece**

1. Medicinal products produced in Greece which cannot exactly correspond as to the pharmaco-technical form, to reference medicinal products authorised and priced in the domestic pharmaceutical market, obtain a price which shall be determined on the basis of a cost assessment that shall include the cost of production and packaging for each form and pack size, the cost of Administration-Marketing-Distribution as determined by relevant tables updated every two years and reflecting the respective average costs in the industry.

2. The following shall not be considered as cost elements: a) default interest; b) personal taxes (income tax, etc.); c) cost of violations of applicable provisions; d) third-party commissions and other costs not related to the production or marketing of medicinal products. In order for the raw materials cost to be determined, the respective cost that results after the reverse reduction of the applicable or resulting price of the reference medicinal product with a similar pharmaco-technical form is taken into account.

3. In case of Greek-patented medicinal products involving research on active substance or pharmaceutical form, for which there are clinical

pharmacokinetics trials and a marketing authorisation by EOF, the cost assessment shall additionally take into account the value of new investment, the cost of research and development of the active substance or pharmaceutical form and a valuation of know-how.

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

5. Until the issue of the prices bulletin of July 2014, EOF will collect the necessary data for the preparation of an updated list with the specific products and for the calculation of the prices, in accordance with the provisions hereof. On the first application of this decision and thereafter, 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, 2.5% for products with a retail price ranging from Euro 6.00 to 11.99 and 5% 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 management period, pharmaceutical companies shall be required to file to the Directorate of Medicines and Pharmacies and the Directorate of Medicines Prices, the following data: Within a period of one month, volume and value data on their sales during the management period under review, within a period of four months, the balance sheet and expenditure statement (detailed and in summary form). The submission of the aforementioned data shall be a prerequisite for the consideration of any request for the approval or revision of a price.

2. A cost audit or audit of individual data of companies shall be carried out, where necessary, independently from any tax or other audit, by officers of Ministry of Health at the registered office of the company; the latter shall be required to provide auditors with access to all its accounting books and records. The competent Service, if it deems it necessary, may use data from related companies and any other available data.



3. Companies producing or importing other goods apart from medicinal products, shall keep separate accounts for their pharmaceutical business. The same obligation shall apply to companies that manufacture or pack medicinal products on behalf of third parties (contract manufacturing) in respect of such products.

4. Pharmaceutical industries shall be required to keep a cost book for the medicinal products they manufacture or pack. Entries in the cost book shall reflect, for each form of medicinal product in detail and by batch, the quantities and cost of raw materials, additional materials and packing materials used, as well as the production/packaging costs of the medicinal products. Moreover, the cost book shall show the quantities produced and their value at ex-factory prices. At the end of the year, the General Industrial Costs corresponding to the production of each medicinal product shall be entered. Before its use, the cost book shall be authorised by the competent service. Companies which, under the Code on Tax Books and Records or other legislation, are required to record these data in a book or in a card-based system shall be exempted from the obligation to keep a cost book.

5. Pharmaceutical industries, agents/importers, wholesalers and pharmacists shall be required to provide to the competent Service any relevant information as may be requested by the Service, in accordance with the provisions of Article 30 of Legislative Decree 136/1946 (on the Market Control Code).

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

## **Article 12**

### **Submission of supporting documents and deadlines for pricing**

1. For the purpose of determining the prices of medicinal products for which a marketing authorisation has been granted by EOF or by the European Medicines Agency (EMA), change of their price may be requested, for which the relevant application shall be required. Applications shall be submitted at the competent Service or emailed to [price\\_list@eof.gr](mailto:price_list@eof.gr), notified to Directorate of Medicines and Pharmacies of the Ministry of Health, as well as to the mail address [farmaka.times@yyka.gov.gr](mailto:farmaka.times@yyka.gov.gr).

2. For all medicinal products of foreign origin (manufactured, packed, imported abroad), a certificate by the foreign company, authenticated by the relevant authorities, shall be submitted to the competent Service, stating the ex-factory price, the wholesale and retail price of the medicinal product in its country of origin.

3. In the case of an application for the pricing of a new medicinal product, the competent Service shall issue a Price Bulletin within 90 days of receipt of the application, **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 appeal against the decision. If the application for the pricing of a new medicinal product is not accompanied by the respective marketing authorisation, the application shall be archived without being processed.

4. In the event of an exceptional number of applications or in exceptional circumstances, the period may be extended for a number of days. In the case of an application for an increase in the price, the provisions of the respective articles hereof shall apply. The applicant shall provide adequate information including details of those events intervening since the price of the medicinal product was last determined which justify the price increase requested. In the event of an exceptional number of applications, the period may be extended once for a further 90 days.

5. A marketing authorisation holder may request the deletion of his medicinal products from the Price Bulletin, provided they can prove that they have given to EOF a three months' notice of discontinuation of the marketing of such products. In these cases, the provisions of Articles 5 and 6 hereof shall be taken into account.

6. For the determination of the price of medicines for which an authorisation for parallel import has been granted by EOF, or for the change of their price, a relevant application shall be required. Such applications shall be filed to the competent service **and** emailed to: [price\\_list@eof.gr](mailto:price_list@eof.gr), **notified to Directorate of Medicines and Pharmacies of the Ministry of Health, as well as to the mail address [farmaka.times@yyka.gov.gr](mailto:farmaka.times@yyka.gov.gr)**. Furthermore, a Solemn Declaration under Law 1599/86 shall be submitted, stating the price of purchase from the supplier with an official sale invoice for the imported quantity attached thereto.

## **Article 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). Large (hospital-size) packages may not be sold in parts by pharmacies.
2. Medicinal products designated by their marketing authorisation as being “EXCLUSIVELY FOR HOSPITAL USE” shall be required to indicate clearly and in a special box on their outer package and in the enclosed leaflet the words “FOR HOSPITAL USE ONLY”.
3. The outer package of medicinal products must indicate the retail price. For the OTC medicinal products, the indicated retail price is suggestive and constitutes the maximum retail price.
4. Transport costs for bringing medicinal products to the facilities of regional wholesalers and pharmacies shall be borne by manufacturers or importers. Such costs shall be borne by wholesalers in respect of products sold to regional pharmacies. By way of exception, wholesalers shall bear no transport costs for orders not exceeding 10 Euros in value.
5. In the event of a price freeze of medicinal products or of certain categories of medicinal products imposed by the competent authorities of the Member State, a review shall be carried out, at least once a year, to ascertain whether the macroeconomic conditions justify that the freeze be continued unchanged.
6. In exceptional cases, the marketing authorisation holder can ask for a deviation of the price freeze, if there are special reasons justifying it. The application must include adequate description of these reasons. The member states ensure a justified decision is taken for every such application and that it is notified to the applicant within 90 days.
7. Manufacturers, packers and importers of medicinal products shall be required to withhold a levy in favour of the Hellenic Association of Pharmacists (0.4% of the wholesale price) for their sales to pharmacies. The levy shall be collected and transferred to the Hellenic Association of Pharmacists through the Pension Fund for Health Professionals (TSAY). Wholesalers shall respectively withhold the levy from pharmacists. For medicinal products exported by wholesalers, the proportion of the levy corresponding to exports (and already withheld by pharmaceutical

companies) shall be returned to wholesalers by the same procedure as in the case of other levies in favour of third parties under similar circumstances. This percentage shall fully borne by the purchasing pharmacies and shall be collected and transferred to the National Pharmacy Association by the aforementioned sellers/invoicing parties. The necessary supporting documents for the reimbursement of the resources are specialised by the resolution of the Board of Directors of the Hellenic Association of Pharmacists and will be the same with those filed to the Tax Authorities for the return of the exports VAT, based on the law in force from time to time. The requests for the reimbursement of the resource with the necessary supporting documents from the wholesalers will be filed to the Hellenic Association of Pharmacists not later than the end of the 5<sup>th</sup> month from the end of the six-months period to which they relate. More specifically, for the exports effected within the first six-months period of each year, the requests will be filed not later than November 30 of the current year, and for the exports effected within the second six-months period of the current year, the request will be filed not later than May 31 of the next year. In order for the timely nature of the requests to be decided, for the purposes of reimbursing the 0.4%, the date recorded on the shipping documents will be taken into account as the starting point, which (shipping documents) prove the dispatch of the medicinal products from one state to the other. Clearance and reimbursement of the withheld contributions will be effected within six (6) months from the date the request and the supporting documents were lawfully filed.

~~8. In the case of co-marketing products, a single price shall be determined. If different prices are derived, the single price shall be the lowest of these different prices.~~

## **Article 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.

The Ministerial Decision 57408/14-06-2013 (Gov. Gazette B' 1446), is hereby repealed.

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