Ministerial Decision Nr. DYG3(a)/oik.97018

Provisions on the pricing of medicinal products

THE DEPUTY MINISTER OF HEALTH

Having regard to:

(...)

WE DECIDE AS FOLLOWS:

Article 1

Definitions

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

2. "Maximum Retail Price" is the price at which medicinal products are sold by pharmacies to consumers, plus the pharmacy margin and VAT. Maximum retail prices shall be uniform across the country, excluding the regions where lower VAT rates apply.

3. "Net price of producer or importer (ex-factory)" is the price at which medicinal products are sold by importers, manufacturers or packers to wholesalers. The net price shall be determined on the basis of the wholesale price reduced: a) for non-prescribed medicines (OTC) by 7.24%; b) for prescribed medicines not reimbursed by social security funds by 5.12%; and c) for prescribed medicines reimbursed by social security funds, 4.67%.

4. "Maximum hospital price" is the price at which medicinal products are sold by importers, manufacturers or packers to the State, public hospitals, Social Care Units, EOPYY pharmacies and the legal entities of public law referred to in para 1 of Article37 of Law 3918/2011, pharmacies of private hospitals with over 60 beds and the relevant pharmacies and wholesalers for the medicinal products of para 2 of Article12 of Law 3816/2010.

The maximum hospital price shall be determined on the basis of the wholesale price reduced by 13%.

5. In particular for medicinal products within the scope of para 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 to obtain the Special Wholesale Price. On the resulting price, a fixed amount of €30 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 any of the medicinal products of para 2 of Article 12 of law 3816/2012 which are included in the list, given their special administration regime, and whose price is lower than €200, the special method of the determination of the retail price at which they are to be sold by private pharmacies shall be determined on the basis of the hospital price, at which 2% is added as a wholesaler's profit margin (Special Wholesale Price), and on the resulting price a percentage of 16% as the pharmacy's profit margin is added. The VAT shall be added to the final price.

7. "Reference medicinal product" shall mean a medicinal product which has been authorised under Article 6 of Joint Ministerial Decision DYG3a/oik.82161/24.8.2012 (Government Gazette 2374/b/24.8.2012) in accordance with the provisions of Article 8 thereof.

8. "Generic medicinal product" shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form.

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

Article 2

Profit margins

1. For wholesalers, gross profit margins shall be determined as follows:

a) for non-prescription medicines (OTC), at 7.8% on the ex-factory price;

b) for prescription medicinal products not reimbursed by social security funds, at 5.4% on the ex-factory price;

c) for medicinal products reimbursed by social security funds, at 4.9% on the ex-factory price; and

d) for the medicinal products of para 2 of Article12 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-prescription medicines (OTC), at 35% on the wholesale price;

b) for prescription medicinal products not reimbursed by social security funds, at 35% on the wholesale price;

c) for medicinal products reimbursed by social security funds 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 listed f in para 2 of Article12 of Law 3816/2010 and having a Special Wholesale Price of up to €200, the profit margin of private pharmacies shall be determined at 16% on the Special Wholesale Price.

Article 3

Discounts - Credit

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

2. Manufacturers, packers and importers may, without any quantitative restrictions, offer a discount on the wholesale prices for the products included in the OTC list. For all other products, manufacturers, packers and importers may offer a discount of up to 5% to wholesalers, pharmacies and cooperatives, provided that the amount of the discount is indicated in the sale invoice.

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

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

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

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

Article 4

Pricing of reference medicinal products

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

shall be converted to ex-factory prices using a methodology and rates as announced from time to time by the competent service of EOF, as well as any other relevant information and data used in the pricing.

2. The following information shall be deemed essential for price-setting: a) name of medicinal product; b) active substance; c) strength in active substance; d) pharmaceutical form; e) pack size; f) ATC classification; g) the person responsible for the marketing; and also the prices (wholesale and/or retail, and/or hospital and/or ex-factory) and the expiry date of the 10-year patent protection or, where appropriate, the 11-year patent protection under Article 10 para 1 subparagraph (b) of the Joint Ministerial Decision DYG3a/oik.82161/24.8.2012 (Government Gazette 2374/B/24.8.2012), or the 6-year patent protection for medicinal products whose market authorization was issued prior to the entry into force of the Joint Ministerial Decision DYG3a/83567/2005 (Government Gazette B 59) under Article 150 thereof. For the price determination, the product must have been priced and be marketed in at least three EU Member States.

3. The prices of on-patent reference medicinal products, according to the pharmaceutical legislation, shall be determined on the basis of the average of the three lowest prices of the respective products in EU Member States.

4. Data reported by pharmaceutical companies via Price Verification Sheets may additionally be taken into consideration. Any sale invoices shall not be considered as valid data in this respect. An electronic template of the Price Verification Sheet shall be prepared by the competent services and forwarded to all pharmaceutical companies. It shall be completed and signed by the person responsible for the marketing of each medicinal product and shall be deemed a legally binding solemn declaration under Law 1599/86. The Price Verification Sheet shall include as mandatory fields: a) the EU Member States in which the product is marketed; b) the name of the product (same or different from the one used in Greece); the active substance, all the forms, pack sizes, strengths and their respective prices; ATC classification; the EOF code, as well as the start and expiry date of the first national or European patent for the active substance of the medicinal product. The Price Verification Sheet shall be completed twice a year; the exact dates shall be specified

by the relevant service of EOF. Price Verification Sheets, submitted exclusively at the competent department, may be forwarded by the competent service or by companies to EOF for further processing. Following the opinion of the Pricing Committee prices may not be issued for those medicines, that have not submitted the above data.

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

6. Any companies which withhold information or for any reason whatsoever fail to report or are found to have reported inaccurate or false data, and this is certified, the competent Service, following an opinion from the Pricing Committee, shall impose a fine, by decision of the Minister of Health in accordance with the provisions of Article 69 of Law 3984/2011.

7. The submission of applications, Price Verification Sheets, enquiries, data and any other communication between pharmaceutical companies and the Department of prices of medicines shall also be possible via the e-mail address farmaka.times@yyka.gov.gr .

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

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

Article 5

Procedural matters regarding pricing

1. On the basis of the data set out in Article 4, the competent service of EOF shall assign prices to medicinal products taking into account, cumulatively, the criteria of paras 2 and 3, where possible. Otherwise, and only for the first price bulletin following the present, extrapolations and correlations with strengths and pack sizes shall be carried out, by applying the provisions of Article12 hereof.

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

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

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

Article 6

Pricing of reference medicinal products after the expiry of the protection period under Article 10 para 1 subparagraph b of Joint Ministerial Decision DYG3a/oik.82161/24.8.2012 (Government Gazette 2374/B/24.8.2012)

1. After the verification by any appropriate method of the expiry of the 10-year or 11-year, as appropriate, protection period under Article 10 para 1 subparagraph b of the Joint Ministerial Decision DYG3a/oik.82161/24.8.2012 (Government Gazette 2374/B/24.8.2012), and respectively of the 6-year period for products authorised prior to the entry into force of Joint Ministerial Decision DYG3a/83657/2005 (Government

Gazette B 59), the wholesale prices of reference medicinal products shall be reduced by 50%, without an application by the marketing authorisation holder.

2. Pharmaceutical companies must indicate in the Price Verification Sheet data on the medicinal product concerned, including full EOF-assigned code, start and expiry date of the first national or European patent protecting the active substance of the medicine, as well as the requested price. Otherwise, a fine shall be imposed by decision of the Minister of Health in accordance with the provisions of Law 3557/2007 and Article 69 of Law 3984/2011. Following the opinion of the Pricing Committee, any products that fail to comply with the aforementioned information requirement may be excluded from pricing.

3. At the first implementation of this Decision, the prices of products fallen out of protection (as defined in paragraph 1 of this article) shall be determined at 50% of the latest price assigned to the product while under protection, if such price is lower than the latest published price in the Price Bulletin. Until EOF, in collaboration with recognised international and national agencies develops a full database with all necessary information, the price reduction of 50% for medicines whose patent protection expired from 2001 until 2005, applies on the highest price that has been assigned to them by a price bulletin until the expiry of the protection period. Furthermore, the prices of medicinal products authorised prior to 2000 shall be reduced by 10%, if their retail price is over €10.00, by 5% if their retail price is between €5.00 and €10.00 and by 3% if their retail price is less than €5.00. The percentage reductions under the preceding sentence shall be calculated and applied on the respective prices as per the current Price Bulletin in force. The provisions of article 4 hereof apply to the categories of medicines that EOF will propose with the concurrent opinion of the Pricing Committee, i.e. to the medicines whose patent protection has expired but there are no generics marketed.

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

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

6. The final wholesale price shall be determined as the lower of the prices resulting under paragraph 1, paragraph 2 (adjusted to the wholesale price level), paragraph 3 and paragraph 5 of this article.

Article 7

Generic medicinal products

1. The wholesale prices of generic medicinal products shall be reduced to 40% of the latest price of the reference product under protection of the patent. At the first implementation of this Decision, the prices of existing generic medicinal products shall be determined at 40% of the latest price assigned to the reference patented product, if such price is lower than the price published in the latest Price Bulletin. Exceptionally until EOF, in collaboration with recognised international and national agencies develops a full database with all necessary information, the prices of medicinal products authorised prior to 2000 shall be reduced by 10%, if their retail price is over €10.00, by 5% if their retail price is between €5.00 and €10.00 and by 3% if their retail price is less than €5.00. The percentage reductions under the preceding sentence shall be calculated and applied on the respective prices as per the current Price Bulletin in force.

3. If the reference medicinal product has a different pack size or strength, a correlation shall be carried out in accordance with the provisions of Article 12 hereof. A similar correlation shall also take place when the price of the original product is priced in a different form or strength. In this case, the other cost parameters shall also be considered. When a generic medicinal product corresponds to a reference product not marketed in Greece, its price shall be determined in accordance with the provisions of Articles 5, 6 and 7 hereof, following a recommendation from the competent department of EOF and the opinion of the Pricing Committee.

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

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

Article 8

Medicinal products manufactured in Greece

1. For medicinal products authorised and priced in Greece and not marketed in any other EU country, the prices shall be determined on the basis of a cost assessment that shall include the cost of production and packaging for each form and pack size, the cost of administration-marketing-distribution costs 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 components: a) default interest expenses; b) personal taxes (income tax, etc.); c) cost of non-compliance with applicable provisions; d) any difference in the price of active substances charged by any supplier in excess of the price charged by the developing laboratory; e) third-party fees and other costs not related to the production or marketing of medicinal products.

3. In the case of Greek-patented medicinal products involving research on active substance or pharmaceutical form, for which there are clinical pharmacokinetics trials and a marketing authorisation by EOF, the cost assessment shall additionally take into account the value of new investment, the cost of research and development of the active substance or pharmaceutical form and a valuation of know-how. Similar pharmaceutical forms shall be exempted from this provision.

4. The maximum net profit margin shall be 8.5% of the total cost excluding depreciation, interest and third-party profits (contract manufacturing). In any event and during the 10-year protection under Article 10 para 1 subparagraph (b) of Joint Ministerial Decision DYG3a/oik.82161/24.8.2012 (Government Gazette 2374/B/24.8.2012), the price of the medicinal product may not be higher than the average of the prices of the medicinal products in the same ATC 4 category, compared with products of the same form and strength.

Article 9

Obligations of pharmaceutical companies

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

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

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

3. A company producing or importing other goods, apart from medicinal products shall keep separate accounts for its 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 companies 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 Documents

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 companies, 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 months' supply per product code, based on the sales of the previous year.

Article 10

Submission of supporting documents and deadlines for pricing

1. For the purpose of determining or adjusting the prices of medicinal products for which a marketing authorisation has been granted by EOF or the European Medicines Agency (EMEA), an application shall be required. Applications shall be submitted at the competent Service or emailed to 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. If the information supporting the application is inadequate, the applicant shall be notified of what additional information is required, and the final decision shall be taken within 90 days of receipt of this additional information. If the decision results in a price that is significantly different from the price requested in the application, the Service shall justify its pricing decision to the applicant and the applicant may appeal against the decision. If the application for the pricing of a new medicinal product is not accompanied by the respective marketing authorisation, the application shall be archived without being processed.

4. In the event of an exceptional number of applications or in exceptional circumstances, the period may be extended for a number of days. In the case of an application for an increase in the price, the provisions of Articles 4, 5, 6, 7 and 8 hereof shall apply. The applicant shall provide adequate information including details of those events intervening since the price of the medicinal product was last determined which justify the price increase requested. In the event of an exceptional number of applications, the period may be extended once for a further 90 days.

5. Marketing authorisation holders may request the deletion of their 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 6 and 7 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 submitted to the competent service or emailed to: 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 11

General provisions

1. The prices of medicinal products shall be determined for the pack sizes approved by EOF and the European Medicines Agency (EMEA). Large (hospital-size) packages may not be sold in parts by pharmacies.

2. Medicinal products designated by their marketing authorisation as being "exclusively for hospital use" shall be required to indicate clearly and in a special box on their outer package and in the enclosed leaflet the words "FOR HOSPITAL USE ONLY".

3. The outer package of medicinal products must indicate the retail price.

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 in value.

5. In the event of a price freeze, the Ministry of Health shall carry out a review, at least one a year, to ascertain whether the macroeconomic conditions justify that the freeze be continued unchanged.

6. In exceptional cases the market authorisation holder can ask for a deviation of the price freezing 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. Pharmaceutical packages intended for export shall not be subject to controls by the Market Control Police. The authenticity tags of the packages which are destined for export are destroyed indelibly and they are submitted to EOF.

7. Manufacturers, packers and importers of medicinal products shall be required to withhold a levy in favour of the Panhellenic Association of Pharmacists (0.4% of the wholesale price) for their sales to pharmacies. The levy shall be collected and transferred to the Panhellenic 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/invoicers.

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

Article 12

Prices in the event of a change of the manufacturer or packer of a medicinal product or of replacement or addition of a pack size of a medicinal product, etc.

1. If the manufacturer and/or the packer of a medicinal product changes, the price of the product prior to the change shall be taken as a maximum.

2. In the event of a replacement or addition of a pack size or strength of a medicinal product or an addition of a variation (provided that the variation refers to the same route of administration), the determination of the price shall involve a correlation with the prices determined as specified in the preceding articles hereof. For the correlation of medicinal products priced under Article 8 hereinabove, any change in packaging/standardisation costs shall be taken into account.

3. The conversion of packages and strengths shall take place as follows:
a) From a smaller to a larger pack/strength, the unit price shall diminish up to a maximum of 12%, as follows:

Percentage increase in pack size/strength	Percentage reduction in price
up to 5	1,67
from 5.01 to 10	3.18
from 10.01 to 15	4.56
from 15.01 to 20	5.83
from 20.01 to 25	7.00
from 25.01 to 30	8.08
from 30.01 to 35	9.07
from 35.01 to 40	10.00
from 40.01 to 45	10.86
from 45.01 to 50	11.67
from 50.01 to 60	12.00

over 60	On a case-by-case basis, taking into account the available data

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

Percentage reduction in pack size/strength	Percentage increase in price
up to 5	1.32
from 5.01 to 10	2.78
from 10.01 to 15	4.41
from 15.01 to 20	6.25
from 20.01 to 25	8.33
from 25.01 to 30	10.71
from 30.01 and over	12.00

c) As an exception, the forms of single-dose injectable preparations, sachets and eye solutions shall be calculated pro rata.

4. When two or more strengths of the same medicinal product are priced and the prices derived are disproportional to each other, the lowest price shall be taken.

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

6. Interested parties may, within three (3) business days of the date after the meeting of the Pricing Committee, provide feedback on the resulting prices. This period shall be extended by two (2) business days in the case of Price Bulletins representing a general revision of the prices of medicinal products. The feedback from interested parties shall be reviewed and addressed by a corrective Price Bulletin within twenty (20) days.

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

Article 13

Authenticity tag or barcode of medicinal products

The requirement to indicate the necessary data on the authenticity tag 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.

Ministerial Decisions DYG3(a)/oik.33013/29-3-2012 and DYG3(a)oik.45414/2-5-2012 are hereby repealed.

We order that this Decision be published in the Government Gazette, entering into force as of such publication.

Athens, October 8, 2012

THE ALTERNATE MINISTER OF HEALTH
MARIOS SALMAS