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Decision no. 32535

Provisions on the pricing of medicinal products

THE MINISTER OF HEALTH

Having regard to:

A. The provisions of:

1. Article 17 of Legislative Decree 96/1973 (Government Gazette A 172) “On the marketing of pharmaceutical, dietetic and cosmetic products in general”, as amended by Article 161 of Law 4600/2019 (GG A 43) “Modernisation and reform of the regulatory framework for private hospitals, establishment of a National Organisation of Public Health, establishment of a National Cancer Institute, and other provisions”;

2. Article 22 of Law 4213/2013 (GG A 261), as amended by Article 90 of Law 4583/2018 (GG A 212) “Abolition of provisions on cuts in pensions, transposition into Greek legislation of Directive 2016/97/EU of the European Parliament and of the Council of 20 January 2016 on the distribution of insurance products, and other provisions”;

3. Law 1316/1983 (GG A 3) “Tasks of the National Organisation of Medicines (EOF) ... and other provisions”, as currently in force;

4. Presidential Decree 142/1989 (A 68) “Statute of the National Organisation of Medicines”;

5. Law 2859/2000 (A 248) “Ratification of the Value Added Tax Code”, as currently in force;

6. Law 3918/2011 (A 31), “Structural changes in the Health System and other provisions”, as currently in force;

7. Law 4052/2012 (A 41) “Law within the remit of the Ministry of Health and the Ministry of Labour and Social Security, implementing Law ‘Approval of draft financial facility agreements … the economy’, and other provisions”, as currently in force;

8. Article 49 of Law 4486/2017 (A 115) “Supply of medicines to private hospitals”;

9. Law 4512/2018 (A 5), Article 259(3), “Implementation of structural reforms under the Economic Adjustment Programme, and other provisions”;

10. Law 4600/2019 (A 43) “Modernisation and reform of the regulatory framework for private hospitals, establishment of a National Organisation of Public Health, establishment of a National Cancer Institute, and other provisions”;

11. Article 90 of Presidential Decree 63/2005 “Codification of legislation on government and government bodies” (A 98);

12. Presidential Decree 121/2017 (A 148) “Statute of the Ministry of Health”, as currently in force,

13. Presidential Decree 73/2015 (A 116) “Appointment of Ministers, Alternate Ministers and Deputy Ministers”;

14. Joint Ministerial Decision Δ.ΥΓ3α/Γ.Π. 32221/2013 of the Ministers of Development, Competitiveness, Infrastructure, Transport and Networks and Health (B 1049) “Harmonisation of Greek legislation with EU legislation on the manufacturing and marketing of medicinal products for human use, in compliance with Directive 2001/83/EC on the Community code relating to medicinal products for human use (L 311/28.11.2001), as currently in force and as amended by Directive 2011/62/EU as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ L 174/1.7.2011);

15. Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems; and

B. Document Β2β/ΓΠοικ.28712/12.04.2019 of the Directorate-General for Economic and Financial Affairs of the Ministry of Health, confirming that the provisions hereof do not imply any burden on the State Budget;

Hereby decides as follows:

Article 1

Purpose

The present Ministerial Decision lays down technical provisions and modalities regarding the pricing rules and procedure for medicinal products marketed in the Greek territory.

Article 2

Definitions

Exclusively for the purposes and within the scope hereof, the following definitions shall apply:

1. Reference medicine: any medicinal product authorised pursuant to Article 7 of Joint Ministerial Decision 32221/29.04.2013 (B 1049) and in accordance with the provisions of Article 9 thereof;

The status of a medicinal product as a reference medicine during its data protection period (on-patent), as a reference medicine after the end of its data protection period (off-patent), as a generic/hybrid/biological/biosimilar/orphan medicine, as a medicinal product of well-established medical use or as a fixed combination of medicinal products, shall be determined by the National Organisation of Medicines (EOF), using the legal basis according to which the marketing authorisation is granted.

2. Reimbursed medicines: prescription medicinal products that are reimbursed by Social Health Insurance Organisations (SHIOs).

3. Non-reimbursed medicines: prescription medicines that are not reimbursed by SHIOs;

4. Maximum ex-factory price: the price at which a medicinal product is sold by the Marketing Authorisation Holder (MAH) to wholesalers, as calculated in accordance with the provisions hereof. The maximum ex-factory price shall be calculated on the basis of the maximum wholesale price, reduced by:

(a) 4.67% for reimbursed medicines priced at up to EUR 200.00, or 1.48% for reimbursed medicine priced at or above EUR 200.01; and

(b) 5.12% for non-reimbursed medicines.

5. Maximum wholesale price: the price at which medicinal products are sold to pharmacies. This price shall include the gross profit margin (mark-up) of licensed

wholesalers, calculated as a percentage of the maximum ex-factory price in accordance with the provisions of Article 5 hereof.

6. Maximum retail price: the price at which medicinal products are sold by pharmacies to consumers; it shall be determined by the maximum wholesale price, adding the pharmacy mark-up as specified by the provisions of Article 5 hereof, plus value added tax (VAT).

7. Maximum hospital price: the price at which medicinal products are sold by MAHs to the public sector, public hospitals, social care units, EOPYY pharmacies, the legal entities in public law referred to in paragraph 1 of Article 37 of Law 3918/2011 (A 31), and private hospitals. The maximum hospital price shall be determined by the maximum ex-factory price reduced by 8.74%.

Article 3

Administrative procedure for pricing – Conditions for inclusion in the price bulletin

1. The pricing of a medicinal product shall require an application by the MAH addressed to the Pricing Department of EOF after a marketing authorisation has been granted by EOF (national, mutual recognition, decentralised procedure) or, in the case of medicinal products authorised under the centralised procedure, in accordance with the provisions of Regulation (EC) 726/2004, after EOF has assigned the nine-digit EOF code, as certified in writing by EOF.

2. A MAH seeking the pricing of its medicinal product shall be required to provide:

(a) the company name, place of residence and principal place of business of the applicant MAH;

(b) information on the medicinal product according to its marketing authorisation, namely:

(i) product name in accordance with Article 2 point 23 of Joint Ministerial Decision 32221/2013;

(ii) active substance;

(iii) strength in accordance with Article 2 point 25 of Joint Ministerial Decision 32221/2013;

(iv) pharmaceutical form;

(v) package; and

(vi) ATC (Anatomic Therapeutic Chemical) classification by the World Health Organisation (WHO);

(c) the price(s) assigned to the medicinal product in the other Member States of the euro area. Also, together with the pricing application, the MAH shall submit all the documents and data required depending on the pricing status of the medicinal product in question under the provisions hereof.

3. If, at the time of submission of the application referred to in paragraph 1, the conditions for first-time pricing laid down in paragraph 5 of Article 17 of Legislative Decree 96/1973 (A 172), as replaced by paragraph 4 of Article 161 of Law 4600/2019 (A 43) and by the provisions of Articles 6 and 7 hereof, are not met, the pricing application shall be rejected. The re-submission of an application to EOF for the first-time pricing of the same medicinal product shall be deemed a new application, and the MAH shall be required to re-submit all the documents and data specified by the provisions hereof and to pay the fee required under the relevant provisions.

4. Applications for the pricing of medicinal products shall compulsorily be submitted to EOF's General Register of Incoming Documents and may also be submitted in electronic form, as specified by relevant announcements of EOF. The procedure for submitting pricing applications may be modified by regulatory circulars issued by the President of EOF and posted on the EOF website.

5. The procedure for the first-time pricing of reference/biosimilar/hybrid medicinal products shall be carried out and completed within ninety (90) days of the submission of the pricing application by the MAH. For generic medicines, the procedure for the first-time pricing shall be carried out and completed within (30) thirty days of the submission of the pricing application by the MAH. If the information provided by the above application is incomplete or inappropriate, EOF shall, without delay, inform the applicant accordingly, and the period for the completion of the pricing procedure shall start from the submission by the applicant of all the required information.

6. The prices of all medicinal products shall be revised once a year, and a Revised Price Bulletin shall be issued in April each year.

7. Reference medicines which have been priced and fall off patent shall be priced in accordance with the provisions of Article 7, and their price shall be included in the next price bulletin.

8. The maximum retail, wholesale, hospital and ex-factory prices, as well as the prices of any other prescription medicines subject to a special sale regime, shall be specified in a Price Bulletin issued by the Minister of Health, following a recommendation by EOF.

Before recommending to the Minister of Health, EOF shall post the price bulletin on its website. Each MAH whose medicinal products have been included in the price bulletin may provide comments within three (3) working days starting from the business day following the date when the price bulletin is posted, exclusively on grounds of obvious error in the pricing of its medicinal product. EOF shall accept or reject the comments and shall finalise the price bulletin and recommend to the Minister of Health.

9. The price bulletins shall take effect on the day following their posting on the Ministry of Health's website, unless the price bulletin specifies a later date, which may not be later than forty-five (45) full days after the posting. The ministerial decision to be issued shall contain all the relevant prices, whereas the Ministry of Health's website shall only indicate the manufacturer and the wholesale and retail prices of medicinal products. The Medicines Directorate of the Ministry of Health shall make available an updated list of hospital prices for use by public sector services and entities.

10. A MAH of a medicinal product that has been included in the price bulletin may raise an objection to the published price bulletin before the Minister of Health, within five (5) days starting from the day following the date of the posting of the price bulletin on the Ministry of Health's website. The objection shall be compulsorily submitted online to EOF, in accordance with the procedure set out in a relevant announcement by the Ministry of Health posted on its website. By decision of the Minister of Health, following an opinion from EOF, the objections shall be rejected or accepted, and an amended price bulletin shall be issued and posted on the website of the Ministry of Health, effective as from the date of its posting.

11. Where the MAH raises objections as described above in respect of medicines subject to reference pricing on the basis of the average of the two (2) lowest different prices of the euro area Member States, the only documentation to be admitted and considered shall be that establishing the price of the medicinal product, the type of price (producer, wholesale, retail), the official price discount rates and the effective date of the available price, as derived from the official websites of the competent authorities of the euro area Member States or indicated in original letters from the competent authorities of the euro area Member States officially translated by the Ministry of Foreign Affairs or by a lawyer. Any other documentation (such as data from subscription-based webpages, sale invoices, MAH correspondence) beyond what is strictly and restrictively specified in the preceding sentence shall not be considered.

12. For reasons of orderly organisation and functioning of the market and for ensuring patient access to new medicines, a Price Bulletin for New Medicines, properly prepared by EOF at an earlier time, may be issued at the same time as the annual Revised Price Bulletin, although the producer prices have been calculated at a different time.

13. In exceptional circumstances, the time limits referred to in paragraphs 5 and 6 may be extended by a specifically reasoned decision of the Minister of Health, following a recommendation by EOF.

14. A Price Bulletin solely for the purpose of updating the data concerning the marketing authorisation of priced medicines, as a result of administrative changes (e.g. change of MAH, renaming of the medicinal product, change of route of administration, withdrawal of marketing authorisation) occurring after the publication of the Revised Price Bulletin shall be posted during the second half of the year together with the list of revisions to the indicative prices for the non-prescription medicines referred to in paragraph 6 of Article 5 of Ministerial Decision 38152/2017 of the Minister of Health (B 1761).

15. A MAH may request the removal of its medicinal product from the price bulletin in which it has been included, only if three (3) months prior to the submission of such request the MAH has notified in writing to the relevant services of EOF the termination of the marketing of the product concerned, providing as evidence a certification by EOF. Once the medicinal product has been removed from the price

bulletin, the MAH shall have the right to apply for the pricing of the same nine-digit code after at least thirty (30) months.

16. Medicinal products that have no sales during the last three (3) years prior to the start of the price revision process or no sales for three consecutive years after their first-time pricing shall not be subject to price revision and shall not be included in a Price Bulletin, irrespective of whether or not their authorisation has been revoked by a declaratory act of EOF under paragraphs 4 and 5 of Article 40 of Joint Ministerial Decision 32221/2013. The notion of sales shall also include exports occurring within the above-mentioned period of three (3) years, as evidenced exclusively by export data submitted by the MAH to the relevant database maintained by EOF.

17. If, exceptionally and for reasons of public health, the marketing authorisation of a medicinal product within the scope of the preceding paragraph is excluded from withdrawal, in accordance with the provisions of paragraph 6 of Article 40 of Joint Ministerial Decision 32221/2013, the MAH may apply for the pricing of its medicinal product with a view to its inclusion in the next Price Bulletin for New Medicines to be issued following the application in accordance with the provisions hereof. The application referred to in the preceding sentence shall constitute an application for the pricing of a new medicinal product, and the MAH shall submit all the documents and data required under the provisions hereof and pay the fee specified in the relevant provisions.

Article 4

Pricing and re-pricing methodology

1. In order to determine the prices of medicinal products based on the prices in the euro area Member States, the EOF Pricing Department shall look up the prices applicable in all euro area Member States using the EURIPID database, as well as the official data made public by the competent authorities of individual euro area Member States. Any type of price available (producer, wholesale, retail price) shall be looked up and retrieved if comparable and relevant for the medicinal product in question. In the absence of a comparable and relevant price, the price discount rates applied by the competent authority of the euro area Member State (e.g. for deriving the producer price) shall be applied and, in the absence of such rates, the available prices shall be obtained.

2. The date of EURIPID price data retrieval in the context of first-time pricing or re-pricing procedures shall be announced on the official website of EOF in advance and at least three months prior to the estimated date of publication of the price bulletin. By way of derogation from the rule of the previous sentence, for the pricing of new medicines, price data from other euro area Member States may be retrieved up to the date of price evaluation by the EOF Pricing Department.

3. When examining the prices of the euro area Member States under paragraph 1, EOF may also examine any data on the prices of the medicinal product in question in other Member States of the euro area as such data are declared by the applicant upon submission of the application under paragraph 1 of Article 3. The data referred to in the preceding sentence shall be provided in the form of a Declaration, together with all relevant information, as part of the Price and Data Search Sheets. The Price and Data Search Sheet shall be filled out, signed and submitted by the MAH and shall be deemed a statutory declaration. In addition, the submission of incorrect data or the concealment of data shall incur a fine imposed by the Minister of Health as provided for in paragraph 2 of Article 13 of Law 3408/2005 (A 272). All applications, queries, Price and Data Search Sheets and any other communication from the MAH to the Pharmaceutical Pricing Department of EOF in the context of a pricing/re-pricing procedure shall be submitted online, as specified by relevant notices posted on the EOF official website.

4. The pricing of new medicinal products, regardless of the category they belong to, shall require prior classification, by the Committee for the Evaluation and Reimbursement of Medicinal Products for Human Use referred to in Article 247 of Law 4512/2018 (A 5), into:

(a) potentially reimbursed medicines; and

(b) non-reimbursed medicines.

5. For non-reimbursed medicines, the applicable pricing rules and methodology shall be the same as for potentially reimbursed medicines. Non-reimbursed medicines shall not be subject to repricing.

6. Blood derivatives and vaccines shall be exempted from re-pricing, for the purpose of protecting public health and ensuring adequate supply to meet patients’ needs.

7. For medicinal products that are not subject to re-pricing, the wholesale price, the producer price and the hospital price shall be recalculated, on each occasion of re-pricing, on the basis of the retail price, which shall remain constant. For medicinal products that are subject to re-pricing, either the producer price or the wholesale price shall serve as a starting point for calculation.

8. If, at the request of the MAH, a medicinal product classified as non-reimbursed is included in the Reimbursement List following the opinion of the Evaluation Committee, the provisions hereof on the revision of the prices of reimbursed medicinal products shall apply.

9. The retail prices of medicines that are reclassified from the category of prescription medicines to the category of non-prescription medicines by relevant decisions of EOF or the European Medicines Agency shall be subject to the provisions of Decision 38152/2017 of the Minister of Health (B 1761). Any medicines reclassified from non-prescription to prescription by virtue of relevant decisions of EOF or the European Medicines Agency shall automatically become subject to the provisions hereof.

10. For the purposes of pricing, the various pharmaceutical forms of oral formulations of immediate release shall be deemed as one and the same pharmaceutical form.

11. In extraordinary circumstances and with a view to the unhindered supply of medicines and the protection of public health and patients, EOF may submit reasoned proposals on the application of special pricing criteria, subject to a specifically reasoned decision of the Minister of Health.

Article 5

Profit margins (Mark-ups)

1. For wholesalers, the gross profit margin (mark-up) shall be determined as follows:

(a) for non-reimbursed prescription medicines, as a percentage of 5,4% on the maximum ex-factory price;

(b) for reimbursed and potentially reimbursed prescription medicines, as a percentage of 4.9% on the maximum ex-factory price, when this is up to EUR 200.00;

(c) for reimbursed and potentially reimbursed prescription medicines, as a percentage of 1,5% of the maximum ex-factory price, when the latter is equal to or higher than EUR 200.01.

2. For pharmacies, the mark-up shall be determined as follows:

(a) for non-reimbursed prescription medicines, as a percentage of 35% on the wholesale price;

(b) for reimbursed and potentially reimbursed prescription medicines, according to the following table:

Wholesale price (EUR)	Pharmacy mark-up (%)
0 - 50.00	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 - 1,000	5.50%
1,000.01 - 1,250	5.00%
1,250.01 - 1,500	4.25%
1,500.01 -1,750	3.75%

1,750.01 - 2,000	3.25%
2,000.01 - 2,250	3.00%
2,250.01 - 2,500	2.75%
2,500.01 - 2,750	2.50%
2,750.01 - 3,000	2.25%
>3,000	2.00%

3. The above mark-ups shall apply to reimbursed medicines sold by community pharmacies, including the medicines referred to in paragraph 2 of Article 12 of Law 3816/2010 (A 6). Where these medicines are sold by community pharmacies and are not reimbursed by EOPYY or other public entity, the pharmacy mark-up shall be specified according to the table above.

Article 6

Pricing and re-pricing rules for on-patent reference medicines

1. As a condition for its first-time pricing, an on-patent reference medicine must have been priced, for a given pharmaceutical form, strength and package (nine-digit EOF code), in at least three (3) euro area Member States. Orphan medicines shall be priced even if prices are available in only two (2) euro area Member States.

2. The maximum ex-factory price of an on-patent reference medicine shall be determined as the average of the two (2) lowest different prices in the euro area Member States for the same medicinal product in terms of active substance, pharmaceutical form, strength and package (nine-digit EOF code). In finding the relevant prices, the rules and methodology laid down in Article 4 hereof shall apply. If the prices found are the same in all the Member States of the euro area in which prices are available, the medicinal product shall be priced at that price if the condition in paragraph 1 is met. In any event, the retail price may not be lower than the price resulting on the basis of the Daily Treatment Cost (DTC), which is set at EUR 0.20.

3. In re-pricing a medicinal product within the scope of the present article, the maximum ex-factory price shall be determined using the same rules and methodology

as in its first-time pricing under the provisions hereof. Where a price is available in only one euro area Member State for the 9-digit EOF code of the medicinal product in question, an adjustment for the different package and/or strength shall take place, and the average of the two prices shall be used. If no official prices are available in euro area Member States for the 9-digit code of the medicinal product, adjustment for a different package and/or strength shall be permitted.

4. For different pack sizes or strengths of a medicinal product of the same pharmaceutical form, which has already been priced, the price shall be derived using the procedure described in the preceding paragraphs along with the price resulting from adjustment to already priced medicines under Article 15, taking into account the lowest unit price, and the lowest between these prices shall be selected, which may not be lower than the lowest price in the euro area.

5. In each re-pricing, the price of an on-patent reference medicine shall be reduced by a percentage of up to 10% of the price indicated in the immediately preceding price bulletin if the latter is higher than the average of the two lowest different prices in the euro area Member States, subject to a lower bound equal to the average of the two lowest different prices in the euro area Member States. In any event, the retail price may not be lower than the price resulting on the basis of the Daily Treatment Cost (DTC), which is set at EUR 0.20.

6. In each re-pricing, the price of an on-patent reference medicine shall be increased by up to 10% of the price indicated in the immediately preceding price bulletin if the latter is lower than the lowest price in euro area Member States, subject to an upper bound equal to the lowest price in the euro area Member States.

Article 7

Pricing and re-pricing rules for off-patent reference medicines

1. As a condition for its first-time pricing, an off-patent reference medicine must have been priced, for a given pharmaceutical form, strength and package (nine-digit EOF code), in at least three (3) euro area Member States.

2. The maximum ex-factory price of an off-patent reference medicine, i.e. after the end of its data protection period of ten or, as appropriate, eleven years, as specified in the provisions of the second and fourth sentences of paragraph 1 of Article 11 of Joint Ministerial Decision 32221/2013, shall be determined as the average of the two (2)

lowest different prices in the euro area Member States for the same medicinal product in terms of active substance, pharmaceutical form, strength and package (nine-digit EOF code). In finding the relevant prices, the rules and methodology laid down in Article 4 hereof shall apply. If the prices found are the same in all the Member States of the euro area in which prices are available, the medicinal product shall be priced at that price if the condition in paragraph 1 is met. In any event, the retail price may not be lower than the price resulting on the basis of the Daily Treatment Cost (DTC), which is set at EUR 0.20.

3. In re-pricing a medicinal product within the scope of the present article, the maximum ex-factory price shall be determined using the same rules and methodology as in its first-time pricing under the provisions hereof. Where a price is available in only one euro area Member State for the 9-digit EOF code of the medicinal product in question, that price shall be adjusted to the different package and/or strength, and the average of the two prices shall be used. If no official prices are available in euro area Member States for the 9-digit code of the medicinal product, adjustment to a different package and/or strength shall be permitted.

4. For different pack sizes or strengths of a medicinal product of the same pharmaceutical form, which has already been priced, the price shall be derived using the procedure described in the preceding paragraphs along with the price resulting from adjustment to already priced medicines under Article 15, taking into account the lowest unit price, and the lowest between these prices shall be selected, which may not be lower than the lowest price in the euro area.

5. In each re-pricing, the price of an off-patent reference medicine shall be reduced by a percentage of up to 10% of the price indicated in the immediately preceding price bulletin if the latter is higher than the average of the two lowest different prices in the euro area Member States, subject to a lower bound equal to the average of the two lowest different prices in the euro area Member States. In any event, the retail price may not be lower than the price resulting on the basis of the Daily Treatment Cost (DTC), which is set at EUR 0.20.

6. In each re-pricing, the price of an off-patent reference medicine shall be increased by up to 10% of the price indicated in the immediately preceding price bulletin if the

latter is lower than the lowest price in euro area Member States, subject to an upper bound equal to the lowest price in euro area Member States.

Article 8

Pricing and re-pricing rules for medicinal products of well-established medical use

1. In first-time pricing and re-pricing, the maximum ex-factory price of medicinal products whose active substances have been in well-established use in the Community for at least 10 years, with recognised efficacy and acceptable level of safety, and which are authorised under the provisions of Article 12 of Joint Ministerial Decision 32221/2013, shall be determined:

(a) by the adjustment described in Article 15, by reference to already priced products of similar pharmaceutical form and the same active substance; or

(b) as the average of the two lowest prices in the euro area Member States, either for the same product or for other products of similar pharmaceutical form and the same active substance; where such prices are not available, the price available in one Member State shall be used.

2. In each re-pricing, the price of medicinal products within the scope of this article shall be reduced by a percentage of up to 10% of the price indicated in the immediately preceding price bulletin if the latter is higher than the average of the two lowest different prices in the euro area Member States, subject to a lower bound equal to the average of the two lowest different prices in the euro area Member States. In any event, the retail price may not be lower than the price resulting on the basis of the Daily Treatment Cost (DTC), which is set at EUR 0.20.

3. In each re-pricing, the price of medicinal products within the scope of this article shall be increased by up to 10% of the price indicated in the immediately preceding price bulletin if the latter is lower than the lowest price in the euro area Member States, subject to an upper bound equal to the lowest price in the euro area Member States.

Article 9

Pricing and re-pricing rules for combinations of established active substances

1. In first-time pricing and re-pricing, the maximum ex-factory price of medicinal products within the scope of Article 13 of Ministerial Decision 32221/2013 shall be

determined as the average of the two lowest prices of the euro area Member States, on condition that the same pharmaceutical form, strength and package (nine-digit EOF code) has been priced in at least three (3) euro area Member States. If it is not possible to find prices for the nine-digit product code in three (3) euro area Member States, adjustment to a different package and/or strength shall be permitted.

2. If the medicinal product has not been priced in three (3) euro area Member States, its price may be calculated by reference to other identical products already priced in Greece or products of the same active substance and similar pharmaceutical form that have been priced even in one Member State of the euro area, using the correlation table of Article 15 hereof.

3. In each re-pricing, the price of combinations of established active substances shall be reduced by up to 10% of the price indicated in the immediately preceding price bulletin, if the latter is higher than the average of the two lowest different prices in the euro area Member States, subject to a lower bound equal to the average of the two lowest different prices in the euro area Member States. In any event, the retail price cannot be lower than the resulting price based on the Daily Cost of Treatment (DTC) set at EUR 0.20.

4. In each re-pricing, the price of combinations of established active substances shall be increased by a percentage of up to 10% of the price indicated in the immediately preceding price bulletin if the latter is lower than the lowest price in euro area Member States, subject to an upper bound equal to the lowest price in euro area Member States.

Article 10

Pricing and re-pricing rules for generic medicinal products

1. The price of a generic medicinal product shall be set at 65% of the price of the respective reference product as determined in accordance with the provisions of Article 7 hereof. Where the pack size or strength of the generic product is different from that of the reference product, adjustment under Article 15 for the priced pack size or strength of the reference product shall take place.

2. Where a reference product is not available in Greece, adjustment under Article 15 shall be made for other already priced generic products of the same active substance and similar pharmaceutical form.

3. Any generic medicinal products for which there is no reference product or same generic product on the Greek market shall be priced at 65% of the price of the reference product in the euro area Member States as determined in accordance with the provisions of Article 7 hereof. Where the pack size and/or strength of the generic product is different from that of the reference product, adjustment under Article 15 for the priced pack size or strength of the reference product shall take place, and the price shall be determined at 65% of the resulting price.

4. If it is not possible to determine a price in accordance with the above, the price of the generic medicine shall be calculated on the basis of the average of the two lowest different prices in the euro area Member States, found from among products of the same active substance and similar pharmaceutical form, otherwise, if prices for two (2) countries cannot be found, the generic product shall be priced at the price available in one country.

5. In the cases of paragraphs 3 and 4, the price of a generic product shall be reduced by up to 10% of the price indicated in the immediately preceding price bulletin, if the latter is higher than the average of the two lowest different prices, or the unique price, found in the euro area Member States, subject to a lower bound equal to the average of the two lowest different prices of the euro area Member States or the unique price in the euro area Member States. In any event, the retail price may not be lower than the price resulting on the basis of the Daily Treatment Cost (DTC), which is set at EUR 0.20.

6. In the cases of paragraphs 3 and 4, the price of a generic product shall be increased by up to 10% of the price indicated in the immediately preceding price list, if the latter is lower than the lowest price in the euro area Member States, subject to an upper bound equal to the average of the two lowest different prices in the euro area Member States.

7. In the price revision for the year 2019, if the price of a generic medicine is reduced by more than 10% of the price indicated in the previous price bulletin, all similar generic products shall be priced at 75% of the price of the respective reference product.

Article 11

Pricing and re-pricing rules for hybrid medicinal products

1. As a condition for its first-time pricing, a medicinal product authorised under the provisions of paragraph 3 of Article 11 of Joint Ministerial Decision 32221/2013 must have been priced in at least three (3) euro area Member States for the same pharmaceutical form, strength and package (nine-digit EOF code).

2. The maximum ex-factory price of a medicinal product within the scope of this article shall be determined as the average of two (2) lowest different prices in the euro area Member States for the same medicinal product in terms of active substance, pharmaceutical form, strength and package (nine-digit EOF code). In finding the relevant prices, the rules and methodology of the provisions of Article 4 hereof shall apply. If the prices found are the same in all the countries of the euro area in which prices are found, the medicinal product shall be priced at this price if the condition in paragraph 1 is met. In any event, the retail price may not be lower than the price resulting on the basis of Daily Treatment Cost (DTC), which is set at EUR 0.20.

3. In re-pricing a medicinal product within the scope of this article, the maximum ex-factory price shall be determined using the same rules and methodology as in its first-time pricing under the provisions hereof. Where a price is available in only one euro area Member State for the 9-digit EOF code of the medicinal product in question, that price shall be adjusted for the different pack size and/or strength, and the average of the resulting prices shall be used. If no official prices are available in euro area Member States for the 9-digit code of the medicinal product, adjustment for a different pack size and/or strength shall be permitted.

4. For different pack sizes or strengths of a medicinal product of the same pharmaceutical form, which has already been priced, the price shall be derived using the procedure described in the preceding paragraphs along with the price resulting from adjustment for already priced medicines under Article 15, taking into account the lowest unit price, and the lowest between these prices shall be selected, which may not be lower than the lowest price in the euro area.

5. In each re-pricing, the price of a hybrid medicinal product shall be reduced by a percentage of up to 10% of the price indicated in the immediately preceding price bulletin if the latter is higher than the average of the two lowest different prices in the euro area Member States, subject to a lower bound equal to the average of the two lowest different prices in the euro area Member States. In any event, the retail price

may not be lower than the price resulting on the basis of the Daily Treatment Cost (DTC), which is set at EUR 0.20.

6. In each re-pricing, the price of a hybrid medicinal product shall be increased by up to 10% of the price indicated in the immediately preceding price bulletin if the latter is lower than the lowest price in euro area Member States, subject to an upper bound equal to the lowest price in euro area Member States.

Article 12

Pricing and re-pricing rules for biosimilars

1. As a condition for its first-time pricing, a medicinal product authorised under the provisions of paragraph 4 of Article 11 of Joint Ministerial Decision 32221/2013 must have been priced, for a given pharmaceutical form, strength and pack size (nine-digit EOF code), in at least three (3) euro area Member States.

2. The maximum ex-factory price of a biosimilar product shall be determined as the average of the two (2) lowest different prices in the euro area Member States for the same medicinal product in terms of active substance, pharmaceutical form, strength and package (nine-digit EOF code). In finding the relevant prices, the rules and methodology laid down in Article 4 hereof shall apply. If the prices found are the same in all the Member States of the euro area in which prices are available, the medicinal product shall be priced at that price if the condition in paragraph 1 is met. In any event, the retail price may not be lower than the price resulting on the basis of the Daily Treatment Cost (DTC), which is set at EUR 0.20.

3. In re-pricing a medicinal product within the scope of the present article, the maximum ex-factory price shall be determined using the same rules and methodology as in its first-time pricing under the provisions hereof. Where a price is available in only one euro area Member State for the 9-digit EOF code of the medicinal product in question, that price shall be adjusted to the different package and/or strength, and the average of the two prices shall be used. If no official prices are available in euro area Member States for the 9-digit code of the medicinal product, adjustment to a different package and/or strength shall be permitted.

4. For different pack sizes or strengths of a medicinal product of the same pharmaceutical form, which has already been priced, the price shall be derived using the procedure described in the preceding paragraphs along with the price resulting

from adjustment for already priced medicines under Article 15, taking into account the lowest unit price, and the lowest between these prices shall be selected, which may not be lower than the lowest price in the euro area.

5. In each re-pricing, the price of a biosimilar medicine shall be reduced by a percentage of up to 10% of the price indicated in the immediately preceding price bulletin if the latter is higher than the average of the two lowest different prices in the euro area Member States, subject to a lower bound equal to the average of the two lowest different prices in the euro area Member States. In any event, the retail price may not be lower than the price resulting on the basis of the Daily Treatment Cost (DTC), which is set at EUR 0.20.

6. In each re-pricing, the price of a biosimilar medicine shall be increased by up to 10% of the price indicated in the immediately preceding price bulletin if the latter is lower than the lowest price in euro area Member States, subject to an upper bound equal to the lowest price in euro area Member States.

Article 13

Pricing and re-pricing rules for special categories of medicines

1. For parenteral solutions belonging to ATC classes B05BA, B05BB, B05BC, B05X, and V07AB, uniform prices shall be determined based on the active substances, strengths, pack sizes and other cost elements. The prices of such parenteral solutions shall be subject to the envisaged reductions according to their prices. The prices of these products shall be calculated as the price of one packaging unit (i.e. one piece).

2. Medicines authorised under the provisions of Article 9 of Joint Ministerial Decision 32221/2013 and co-marketed shall be assigned the same lowest price.

3. The price of medicinal products authorised under the provisions of Article 14 of Joint Ministerial Decision 92/322/2013 shall be set at 65% of the price of the reference medicinal product from which they have obtained the consent, whether this is marketed in Greece or in another Member State of the euro area.

4. The prices of medicinal products for which a parallel import license has been issued by EOF shall be determined: (a) on the basis of the prices of the same medicines in the price bulletin, otherwise (b) in accordance with the provisions of the preceding articles. The MAH shall be required to submit a statutory declaration

stating the price at which the product has been purchased from the supplier, accompanied by an officially certified purchase invoice for the import quantity. A change in the price of a medicinal product for which a parallel import license has been issued by EOF shall require the submission of a relevant application and a statutory declaration stating the purchase price paid to the supplier, accompanied by an officially certified purchase invoice for the import quantity.

Article 14

Cost-based pricing and repricing

1. Medicinal products manufactured in Greece:

(a) whose active substance is not already in circulation in Greece; or

(b) for which it is not possible to establish an exact correspondence, in terms of pharmaceutical form and/or dispensing device, to reference medicinal products available on the Greek market, shall be subject to cost-based pricing.

The prices of the above medicines may not be higher than those of the reference products belonging to the same ATC5 class and having a similar pharmaceutical form and corresponding strength.

2. The following items shall not be eligible cost elements:

(a) interest on arrears;

(b) personal tax (income tax, etc.);

(c) expenses incurred for breaches of applicable provisions;

(d) third-party fees and other costs that are not related to the manufacturing and distribution of medicinal products.

3. The costs of active substance(s) shall be evidenced by purchase invoices. For the remaining cost elements, the relevant cost calculation tables shall be used.

4. For those medicinal products which have been granted a Greek patent for research into active substance or pharmaceutical form and for which pharmacokinetic studies and EOF marketing authorisation are available, account shall be taken of the value of new investment, active substance or pharmaceutical form research and development costs, as well as a valuation of know-how.

5. The above shall apply by analogy to re-pricing, and the MAH shall submit a cost table accompanied by the necessary supporting documents substantiating the costs declared.

6. The maximum mark-up shall be set at 8.5% of total cost net of depreciation, interest and third-party profit from outsourced operations.

7. In each re-pricing, the price of the above-mentioned medicinal products may be reduced by up to 10% of the price indicated in the immediately preceding price bulletin. In each repricing, the price of the above-mentioned medicinal products may be increased by up to 10% of the price indicated in the immediately preceding price bulletin, if the price of the reference product increases. In any event, the retail price may not be lower than the price resulting on the basis of the Daily Treatment Cost (DTC), which is set at EUR 0.20.

Article 15

Adjustment coefficients

1. In the adjustment process, the coefficients indicated in the following table shall be used:

(a) From a smaller to a larger pack size and/or strength, the unit price shall be reduced by a maximum of 12%, as follows:

Increase	Decrease in proportionate 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	Ad hoc

(b) From a larger to a smaller pack size and/or strength, the price shall be calculated proportionately per unit of pharmaceutical form [it is indicatively noted that a unit is one (1) tablet, one (1) ml in the case of oral solutions, one (1) gram in creams and ointments, etc.].

2. Excluded shall be single-dose (SD) sachets and ophthalmic solutions, which shall be subject to proportional calculation, as well as monthly packs of the same strength as determined by the average daily dose referred to in the list of reimbursed medicinal products.

Article 16

Discounts and credit

1. MAHs may grant an additional discount on the hospital price, without any limitation, for the medicines supplied to the State, public hospitals, the Social Care Units referred to in Article 37 of Law 3918/2011, EOPYY pharmacies and private hospitals, provided that the amount of the discount is indicated in the sale invoice. MAHs may grant a discount, without limitation, on the producer price for the medicines referred to in paragraph 2 of Article 12 of Law 3816/2010 and up to 10% of the wholesale price for prescription medicines sold to wholesalers, pharmacies and cooperatives, provided that the amount of the discount is indicated in the sale invoice. In the case of medicines sold directly to pharmacies, the discount on the wholesale price shall also include the wholesale mark-up, which is refundable to EOPYY in accordance with the provisions of Ministerial Decision 30468/22.04.2015 (Government Gazette B 869/19.05.2015).

2. Wholesalers may grant a discount of up to 10% for prescription medicines and unlimited discounts to pharmacists for the medicines referred to in paragraph 2 of Article 12 of Law 3816/2010, provided that the amount of the discount is indicated on the sale invoice.

3. MAHs shall sell on credit to pharmacies, wholesalers and cooperatives for at least two (2) months, provided that such credit is indicated in the sale invoice. Wholesalers are required to sell on credit to pharmacies and cooperatives for at least two (2) months, provided that this is indicated in the sales invoice.

4. In the event of non-compliance with the preceding paragraphs, the sanctions provided for by law shall be imposed.

Article 17

Obligations of pharmaceutical companies

1. A cost accounting audit or targeted inspections at companies shall be carried out, where appropriate, independently of any tax or other audit, by officers of the Ministry of Health, at the principal place of business of the pharmaceutical company. The company shall make all its accounting books and records available to the officers of the Ministry of Health. The competent authority may, where deemed necessary, use data of affiliated companies or any other information at its disposal.

2. Companies that also engage in non-pharmaceutical manufacturing or imports must keep separate accounts for their pharmaceutical line of business. The same obligation shall apply to companies contracted to manufacture or package medicinal products on behalf of third parties in respect of such medicinal products.

3. Pharmaceutical companies shall be required to keep a cost book for the medicines they manufacture or pack. Recorded in this book shall be, per pharmaceutical form and per production lot, the quantities and costs of the raw and ancillary materials, the packaging materials used and the manufacturing and packaging costs. Also recorded shall be the quantities produced and their costs at ex-factory prices. At the end of the year, the General Manufacturing Costs related to the manufacturing of the medicinal product shall be recorded. Before use, the cost book must have been certified by the competent authority. Companies that are required by the Code of Tax Books and Records or other legislation to keep such data in a book or card system shall be exempted from the obligation to keep a cost book.

4. Pharmaceutical manufacturers, representatives/importers, wholesalers and pharmacists shall be required to provide any information relating to medicines as may be requested by the Directorate of Medicines of the Ministry of Health or the Pricing Department of EOF.

5. Pharmaceutical companies must have stocks of medicines, by EOF code, sufficient for three (3) months' supply based on the sales of the previous year.

Article 18

General provisions

1. The prices of medicinal products shall be determined for the packages authorised by EOF and the European Medicines Agency (EMA). Hospital-size (large) packages may not be sold in parts by pharmacies.

2. Medicinal products which under their marketing authorisation are designated as "EXCLUSIVELY FOR HOSPITAL USE" shall mandatorily indicate "FOR HOSPITAL USE ONLY" on the outer package and in the enclosed instructions.

3. The retail price of prescription medicines shall be indicated on the outer package.

4. The transport costs for delivering the medicines to the facilities of wholesalers and pharmacies in the Greek provinces shall be borne by manufacturers or importers. The same cost shall be borne by pharmacists for their sales to pharmacies in the Greek provinces. Exceptionally, pharmacists shall not bear the transport costs for the execution of an order involving an amount of up to EUR 10.

5. In exceptional circumstances, the MAH may request an exemption from the freeze on prices if there are specific reasons to justify such exception. The relevant request must include a sufficient description of these reasons. The decision on the request shall be fully reasoned and shall be communicated to the applicant within ninety (90) days.

Article 19

Authenticity tag or barcode for medicines

The obligation to indicate the information provided in the authenticity tag or the bar code shall be without prejudice to the obligation to include these data also elsewhere on the package, as required by other provisions.

Article 20

Entry into force - Repealed and transitional provisions

1. The present Decision shall enter into force as of its publication in the Government Gazette.

2. As from the entry into force hereof, Decision 90552/2016 of the Minister of Health (B 3890) and any other regulatory provision contrary to the provisions hereof shall be repealed.

3. Any pricing or re-pricing procedures currently underway shall be carried out in accordance with the provisions hereof.

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

Athens, 30 April 2019

The Minister

ANDREAS XANTHOS