‘ORGAN DONATION AND TRANSPLANTS AND OTHER PROVISIONS’

Article 68
Positive list of prescription medicines

1. The first and second sub-paragraphs of case c of paragraph 2 of Article 12 of Law 3816/2010 (Government Gazette A’ 6) are replaced as follows:

“By decision of the Minister of Health and Social Solidarity, published in the Government Gazette, approval is granted upon recommendation of the National Organization for Medicines (EOF), to the list of medicines for serious diseases cited in paragraph 2. Using the same procedure, the list is renewed, supplemented or amended to take the form of separate lists at least once per year”.

2. Case d of paragraph 2 of Article 12 of Law 3816/2010 is deleted.

3. Case b of paragraph 1 of Article 12 of Law 3816/2010 is replaced as follows:

“For the purposes of setting up, revising and supplementing the reimbursement list a system of reference prices is introduced for each therapeutic category of medicinal products. The reference price of each therapeutic category is up the maximum reimbursement price paid by the social insurance funds for the medicinal products included in the therapeutic category. If the difference between the prices of the medicinal products and the reference price is positive, it will be returned by the pharmaceutical companies to the social insurance funds, under the condition that the companies have first submitted an application stating their consent to include them in the list and to the established compensation system. If the pharmaceutical companies do not submit the aforementioned application stating their consent, their medicinal products will be automatically excluded from the positive list. The details of the procedure for implementing the system of reference prices are set out by Decision of the Ministers of Health and Social Solidarity and the Employment and Social Insurance and uploaded on the National Organization for Medicines (EOF) website. More specifically, this Decision shall lay down the method for setting up the therapeutic categories, the method for setting the reference price for each therapeutic category, the bodies to which the reference prices must be communicated, the bodies responsible for (and the procedure to be used in) calculation, certification and collection of the amounts returned to the social insurance funds, as well as all other relevant issue. In all circumstances the above regulation shall be implemented independently of the provisions of Article 35 of Law 3918/2011 (A’ 31)”.

4. In case c of paragraph 1 of Article 12 of Law 3816/2010 the words “by joint decision of the Minister of Employment and Social Insurance, the Minister of Health and Social Solidarity and the Minister of the Economy, Competitiveness and Shipping” are replaced by the words “by joint Decision of the Ministers of Health and Social Solidarity and Employment and Social Insurance”.

Article 69
Provisions related to the pricing of medicinal products

1**.** Paragraphs 1 and 2 of Article 17 of Legislative Decree 96/1973 (A'172) are replaced as follows:

"1. The maximum prices for wholesale, hospital, retail and all other special sales of medicinal products are set in Price Bulletins issued by the Minister of Health and Social Solidarity upon recommendation of the Pricing Committee. The Price Bulletins enter into force from the date they are uploaded on the website of the Ministry of Health and Social Solidarity; publication in the Government Gazette is not required. The deadline for the submission of appeals starts from the next day of the upload in the website.

2. The Pricing Committee and the Pricing Department of Medicinal Products may seek the assistance of EOF in matters related to products within its sphere of competence and deemed necessary in the pricing procedure".

2. The provisions of cases c and d of paragraph 5 of Article 17 of Legislative Decree 96/1973 (A'172), as replaced from paragraph 1 of article 14 of law 3840/2010, are replaced as follows:

"c) Prices of original medicinal products, after certification by all expedient means of the expiry of the first national or European patent of the active ingredient of the respective products, are reduced to at least thirty per cent (30%).

The prices of medicinal products with similar active ingredients and pharmaceutical form are set at a maximum of 90% of the sale price of the corresponding original product, whose first national or European patent of the active ingredient of the corresponding medicinal product has expired, as this price is determined every time, in accordance with the current provisions. The procedure for determining prices of medicinal products as set out in the preceding sub-paragraphs is to be implemented ex officio by the Pricing Department of Medicinal Products of the Directorate of Medicinal Products and Pharmacies of the Ministry of Health and Social Solidarity.

d) The price of each medicinal product prepared or packaged or imported into Greece is calculated using the average of the three lowest corresponding prices of the same product in the member states of the European Union where official data exist and are announced by the competent authorities of these countries. For the price determination, the sale price of the product to wholesalers and/or the wholesale price in the member states, where the specific product is sold and where official data are issued by the competent authorities, is taken into account. The price of each medicinal product must be determined by the Pricing Department of Medicinal Products of the Directorate of Medicinal Products and Pharmacies of the Ministry of Health and Social Solidarity up to twice a year. In the case of products not marketed in three countries, the method of determining their price will be determined by the average of the prices in the two member states, where the price is found. If the medicinal product is marketed only in one member state, the lowest price resulting from the current and the price found in the other member state, will be taken into account. The relevant issue is further determined by Decision of the Minister of Health and Social Solidarity".

3. Case h at the end of paragraph 5 of Article 17 of Legislative Decree 96/1973 (A'172), which was added by paragraph 4 of Article 15 of Law 3557/2007 (A'100) is replaced as follows:

"Applications submitted to the Pricing Department of Medicinal Products of the Directorate for Medicinal Products and Pharmacies of the Ministry of Health and Social Solidarity for determining the prices of medicinal products shall be mandatorily accompanied by a fee set at: a) the amount of 300 Euro, in the case of determining the price of a new product, by EOF code, b) the amount of 150 Euro, in the case of an increase in the current sale price of the product, by EOF packaging code number. The resulting income of these fees will be added to the state budget. The amounts of these fees may be adjusted by joint decision of the Minister of Health and Social Solidarity and the Minister of Finance".

4. Paragraph 2 of Article 13 of Law 3408/2005 (A' 272), as replaced by paragraph 2 of article 14 of law 3840/2010, is replaced as follows:

"2. The pharmaceutical companies are obliged to: a) provide the competent Service with data and information, including the price of their product, as required by the competent Service in order to determine the initial price for each product and adjust prices of existing marketed products in accordance with the provisions of the preceding paragraph and b) inform the Pricing Department of Medicinal Products of the Directorate for Medicinal Products and Pharmacies of the Ministry of Health and Social Solidarity about the date the first national or European patent of the active ingredient of their products entered into force. Any pharmaceutical company concealing or refusing to supply information, or supplying false or inaccurate data and information, shall be liable to a fine equal to ten times the difference between the price calculated using the data submitted by the pharmaceutical company and the price set by the Service, multiplied by the quantity of items of the product sold for as long as the approved price was in effect. This fine shall be imposed, pursuant to this paragraph, independently of the claim of the insurance funds for repayment of the losses they have sustained from the above difference in prices of the medicinal products. The legal representative of the pharmaceutical company proven to conceal or refuse to supply or supplying false or inaccurate data and information shall be liable to at least six months of imprisonment. By decision of the Minister of Health and Social Solidarity are determined the bodies, procedure, method and all other relevant issues related to the fine, which shall be deemed to be public income and shall be collected under the provisions of the Code for Collection of Public Revenues (KEDE)".

5. Paragraph 3 of Article 14 of Law 3840/2010 (A' 53) shall be replaced as follows:

"3. The details of implementation of the above provisions shall be determined by Decision of the Minister of Health and Social Solidarity".

Article 70
Provisions relating to pharmacies

1. The two last sub-paragraphs of paragraph 3 of Article 36 of Law 3918/2011 (A' 31) are replaced as follows:

"Within the boundaries of the Region of Attica and the Regional Unit of Thessaloniki, as defined in Law 3852/2010 (A' 87), and in municipalities with a population of more than 100,000 inhabitants, the above ratio of inhabitants to pharmacy will be determined on the level of municipal units on the basis of the most recent census".

2. Paragraph 4 of Article 36 of Law 3918/2011 (A’ 31) is replaced as follows:

“4. The transfer and establishment of pharmacies is permitted, by derogation from the provisions of paragraph 1 of this article, near public hospitals with a capacity of over 150 beds and at a distance of 100 metres on each side of the middle of the main external gate on both construction lines of the street on which the gate is located. The number of new pharmacies may not exceed the number of those already functioning in the area at the time of publication of this Decision”.

Article 71
Miscellaneous provisions

1. The last sub-paragraph of paragraph 1 of Article 38 of Law 3918/2011 (A’ 31) is replaced as follows:

“The net producer’s or importer’s price is to be defined as the wholesale price of the medicinal product reduced by 5.12%”.

2. The last sub-paragraph of paragraph 2 of Article 38 of Law 3918/2011 (A’ 31) is replaced as follows:

“The net producer’s or importer’s price is to be defined as the wholesale price of the medicinal product reduced by 7.24%”.

3. The penultimate and final sub-paragraphs of paragraph 3 of Article 39 of Law 3918/2011 (A’ 31) are to be replaced as follows:

“The Pricing Department of Medicinal Products is to be staffed by one IT expert of graduate grade, two IT experts of technical grade, one economist of graduate grade, two administrators of graduate grade and two pharmacists of graduate grade. The Department will be headed by a pharmacist, or an IT expert, or an administrative expert or an economist of graduate grade”.

4. To the final sentence of instance e of paragraph 3 of Article 17 of Legislative Decree 96/1973 (A’172), as replaced by paragraph 5 of article 39 of Law 3918/2011 (A’ 31), the following words shall be added: “with his deputy”.

5. To Article 39 of Law 3918/2011 (A’31) a new paragraph 6a shall be added, as follows:

“6a. Regulation determining the modus operandi for the Prices and Medicinal Products Committee shall be appointed by Decision of the Minister of Health and Social Solidarity’, and paragraph 7 of the same article shall be re-numbered as paragraph 8.

6. Paragraph 3 of Article 63 of Law 3918/2011 (A’31) shall be amended as follows:

“3. By decision of the Minister of Health and Social Solidarity, issued upon recommendation of the Board of EOF, shall be determined the method of printing –on the part remaining of the authenticity tag on the external packaging after detachment of the moveable part of the tag– of the ‘EAN’ barcodes, the tag serial number and the EOF code number of the product, in such a way as to be indelible”.

7. Case c of paragraph 13 of Article 3 of Law 1316/1983 (A’3), as replaced by paragraph 1 of Article 63 of Law 3918/2011 (A’ 31) is replaced as follows:

“c. By decision of the Minister of Health and Social Solidarity, issued upon recommendation of the Board of the EOF, shall be determined the type of tag, the method of distribution and cancellation, their use and any other relevant issue”.