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DECISIONS

No Γ.Π./ΟΙΚ.12449

Supplementation-Amendment of the Ministerial Decision No οικ.3457, Gov. Gazette B/64/16-01-2014, “Regulation of issues concerning the pricing of Medicinal Products”.

THE MINISTER OF HEALTH

Having considered:

1. The provisions of article 14, par. 3 of Law 3840/2010 (Gov. Gazette A’ 53).
2. The provisions of article 90 of the P.D. 63/2005 “Codification of legislation for the Government and Government bodies” (A’ 98).
3. The P.D. 119/2013 “appointment of the Vice-President of the Government, Ministers, Alternate Ministers and Deputy Ministers” (Gov. Gazette A 153).
4. The provisions of the L.D. 96/1973 and mainly article 17 as amended and in force (Gov. Gazette A 172).
5. The provisions of the L.D. 136/1946 “for the Market Police Code” (Gov. Gazette A’ 298), as amended and in force.
6. The provisions of article 13 of Law 3408/2005, as amended and in force (Gov. Gazette A 272).
7. The provisions of Law 3842/2010 (Gov. Gazette A 58) as amended and in force.
8. The provisions of article 4 par. 2 of Law 3899/2010 ((Gov. Gazette A 212), for the amendment of VAT Code.
9. The provisions of article 32 of Law 1316/1983 “Establishment, Organisation and competencies of EOF” (Gov. Gazette A 3), as already amended and in force.
10. The provisions of the P.D. 95/2000 “Organisation of the Ministry of Health and Welfare” (A’ 76), as amended and in force.
11. The provisions of articles 38, 39, 40 and 51 of Law 3918/2011 (Gov. Gazette A 31) as amended and in force.
12. The provisions of articles 11, 16, 17, 19, 20, 21 and 23 of Law 4052/2012 (Gov. Gazette A 41).

13. The Joint Ministerial Decision (KYA) No ΔΥΓ3α/Γ.Π.32221/2013 (Gov. Gazette 1049/B/29.4.2013), “Approximation of Greek legislation to the respective European one in the area of production and marketing of medicinal products for human use, in compliance with the directive 2001/83/EC “on the Community code relating to medicinal products for human use (Law 311/28.11.2001) as in force and as amended by the Directive 2010/84/EU, regarding pharmacovigilance (Law 348/21.12.2010) regarding pharmacovigilance.

14. The Ministerial Decision No ΔΥΓ3(α)/οικ.86767/10.9.2012 “Revocation of the decision for the application of competencies to EOF regarding the pricing of medicinal products” (Gov. Gazette B 2462).

15. The Ministerial Decision No ΔΥΓ3(α)/οικ.94274/28.9.2012 “Application of article 15 in Law 4052/2012” (Gov. Gazette B 2675).

16. The Decision of the Alternate Minister of Health No ΔΥΓ3(α)/οικ.7789/22-01-2013 (Gov. Gazette B’ 94).

17. The Decision of the Alternate Minister of Health No 57408/14-06-2013 (Gov. Gazette B’ 1446) “Provisions for Pricing of Medicinal Products”.

18. The Ministerial Decision No 69010 (Gov. Gazette 1814/25-07-2013) “Provisions for Pricing of Medicinal Products”.

19. The provisions of the Ministerial Decision No ΓΠ/οικ/90281 (Gov. Gazette 2467/B/02-10-13) “Approval of the positive list set out in article 12(a) of Law 3816/2010”, as amended and in force.

20. The provisions of article 12 of law 3816/2010 (A’6), as supplemented by par. 5 of article 63 of Law 3918/2011 (A’31) and the provisions of article 51 of law 3918/2011 (A’31).

21. The Ministerial Decision No Γ.Υ./ΟΙΚ 6161 (Gov. Gazette 2761/B/30-10-2013).

22. The provision of article 22 of law 4213/2003.

23. The Ministerial Decision No 325/585/ΓΠ (Gov. Gazette 88B/21-1-2014).

24. Article 34 of Law 4025/2011 (Gov. Gazette 228 A).

The fact that no expenditure is incurred against the State Budget from this decision, we decide:

In the first paragraph of article 11 of the Ministerial Decision No 3457, Gov. Gazette B/64/16-01-2014 “Regulation of issues concerning the pricing of Medicinal Products”, the part that starts “... and only in very exceptional and rare cases...” until the end of the paragraph is deleted and substituted by the following “... and additionally, they can be dispersed to public and private hospitals with a capacity of over 60 beds, if they state to the Organisation their inability to administer them, following the procedure that will be defined by the Chairman of EOPYY, after the resolution of the Board of Directors of the Organisation”.

In the first paragraph of article 15 of the Ministerial Decision No 3457, Gov. Gazette B/64/16-01-2014 “Regulation of issues concerning the pricing of Medicinal Products”, the first clause is substituted with the following: “By virtue of the decision

of the Minister of Health, a seven (7) member National Committee for monitoring the pharmaceutical expenditure and the application of the therapeutic prescription protocols is established, with the participation of a representative of EOPYY, which has as its object...” and in the same paragraph, clause (c) is substituted with the following: “...c) The proposing of measures to the Minister of Health and the President of EOPYY in case of transgression of the therapeutic protocols and over-prescribing”. In addition, the third paragraph of article 15 of the above Ministerial Decision is substituted with the following: “3. The responsibility for the co-ordination of the development of therapeutic protocols and their digital imaging, as well as the support of the control and training mechanism of physicians in the application thereof, is vested with the Athens Medical Society, with the co-operation of special scientific medical societies. The responsibility for the preparation of therapeutic protocols, following the relevant invitation of the National Committee, lies with the scientific societies of medical specialties and specialties recognised by the KESY, in cooperation with the Medical Society of Athens. The scientific societies are obliged, to that end, to form Work Groups ensuring the procedures of the strong scientific consent in the development of the therapeutic protocols, with the participation of Unions of patients. In case of denial or inactive participation of the scientific societies, respective work groups may be established, upon the suggestion of the National Committee”.

The first paragraph of article 16 of the Ministerial Decision No 3457, Gov. Gazette B/64/16-01-2014 “Regulation of issues concerning the pricing of Medicinal Products” is substituted with the following: 1. By virtue of the decision of the President of EOPYY, which will be published within one month from the date this decision is published, the prescription limits for each physician cooperating with EOPYY are determined for 2014. More specifically, the monthly expenditure of all prescriptions of each physician may not exceed 80% of the average monthly expenditure thereof during 2013. For this reason, EOPYY calculates the average monthly expenditure per physician for 2013 and sets the limits of the monthly prescription expenditure per physician for 2014. HDIKA adjusts the electronic prescription system so that the physician will not be able to prescribe per month, medicinal products whose total expenditure exceeds the predetermined monthly limit set for each physician. By virtue of a decision of the President of EOPYY, special categories of physicians may be excluded from the application of this decision, such as physicians prescribing medicinal products to Elderly Care Centres (KAPH), work physicians, physicians in NGOs, physicians working in public benefit hospitals, physicians employed in multi-medical facilities of security corps and EOPYY physicians. In addition, the ceiling excludes patients suffering from chronic nephropathy (undergoing dialysis, peritoneal dialysis and transplant), terminal heart patients (mechanical heart, terminal heart failure, heart transplant), patients with liver failure (terminal liver failure and non-balanced cirrhosis, liver transplant), patients who have undergone transplant of liquid or solid parts and tissues. In addition, medicinal products whose use is preliminarily approved by EOPYY through its committees are also excluded. Moreover, the said measure does not apply, throughout 2014, for the physicians in the island of Cephalonia. The physicians of hospitals and private clinics are also excluded from the application of the measure, as regards the medicinal products prescribed to hospitalized patients or patients leaving the hospital, however they fall into the scope of application, as regards the medicinal products prescribed to out-going patients and they are offered by private pharmacies and the pharmacies of EOPYY. The new-

entrants to the Electronic Prescribing physicians or physicians who have obtained a license to operate their first private infirmary by the Medical Association from 2011 and forth, physicians who did not exercise their medical profession in 2013, physicians whose visits have increased to 400 per month, may use the average of their specialty. In addition, the limits of the expenditure per physician are redefined during the year, in proportion to the work produced by the said physician and the course of the total pharmaceutical expenditure, especially for the categories in which new medicinal products are included in the positive list. In addition, the limits may be redefined in exceptional and justified cases, which as assessed on a case-by-case basis. For this reason, by virtue of the decision of the President of EOPYY, a Special Seven-member Committee is formed, with the participation of representatives of EOPYY, HDIKA, EOF, the Hellenic Pharmacies Association and the Hellenic Medical Association. The task of the Committee is the filing of suggestions for the improvement of the application of the measure, the development of criteria that will be applied for the assessment of requests for the increase of the prescribing limits, for specific categories of cases of physicians and the assessment of the relevant requests and the final granting of opinions to the President of EOPYY. EOPYY and HDIKA see that within one month from the publication hereof, the pharmacies of EOPYY will connect to the electronic prescribing system and prescriptions execution, so as to efficiently implement this provision and to constantly monitor the course of the public pharmaceutical expenditure.

In the first paragraph of article 19 of the Ministerial Decision No 3457, Gov. Gazette B/64/16-01-2014 "Regulation of issues concerning the pricing of Medicinal Products" "article 15" is renumbered to "article 16" and the second paragraph is substituted with the following: "2. The object of the National Committee of article 15 also includes the performance of laboratory and diagnostic protocols and more specifically: (a) the selection of the tests and conditions for which laboratory and diagnostic protocols will be developed (b) the conjunction of the above with the therapeutic protocols, c) the determination of a framework and control mechanism for the application of the protocols, (d) the proposing of measures to the President of EOPYY for the more efficient application of the protocols and the control in case of transgression in and over-prescribing, e) the making of suggestions for the improvement of the whole system, with regard to the needs and malfunctions that will emerge, f) the management of any objections by any entity having legal interest. The diagnostic and laboratory protocols will be incorporated in the electronic system for the monitoring of the prescribing and performance of tests and will be connected to the details and the diagnosis of the patient so that limits are set and over-prescribing and useless use of tests and services is avoided. In addition the list with the services and whose cost is reimbursed by EOPYY in accordance with the due and documented medical practice, the international literature and the applicable European standards and respectively, suggestions are filed to the administration for the amendment of the regulation for benefits and the policy of the organisation".

At the end of paragraph 2 of article 5 of the Ministerial Decision No 325/5851/ΓΠ (Gov. Gazette 88 B'/ 21-1-2014) the following clause is added. "The prices bulletin may be published at a later date, when the preparation thereof has not been completed within the aforementioned months of this paragraph".

In the fifth paragraph of article 16 of the Ministerial Decision No 3457, Gov. Gazette B/64/16-01-2014 the first clause is substituted with the following"

“5. For the development of the targeted therapy, within one month from the date of publication hereof, the oncology committee, under the supervision of the National Committee of article 15 hereof, is called to propose a list...”.

This decision must be published in the Government Gazette.

Athens February 7, 2014

THE MINISTER

SPYRIDON ADONIS GEORGIADIS