

**No 4204/2012**  
**THE COUNCIL OF THE STATE**  
**IN PLENARY SESSION**

Met in public before its audience on March 2, 2012, with the following composition: K. Menoudakos, vice Chairman, substituting the Chairman of the Council of the State, who was impeded, Ang. Theophilopoulou, Vice Chairman of the Council of the State, N. Rozos, D. marinakis, M. Karamanov, Ek. Sakellaropoulou, D. Alexandris, D. Skaltsounis, A. G. Voros, G. Potamias, M. Gortzolidou, E. Nika, E. Antonopoulos, P. Karli, F. Tzimas, Sp. Chrysikopoulou, Her. Tsakopoulos, V. Kalantzi, V. Arabantinos, D. Kyriilopoulos, E. Kousiouris, O. Zygoura, V. Raftopoulou, K. Kousoulis, Th. Aravanis, A. Chlabea, M. Pikramenos, members of the Council, T. Komvou, P. Tsoukas, E. Skoura, assistant judges. From the above members, the members of the Council O. Zygoura and K. Kousoulis as well as the deputy judge P. Tsoukas, participate as alternate members, in accordance with article 26, par. 2 of Law 3719/2008. M. Papasaranti acts as Secretary.

In order to rule on the petition dated November 12, 2008:

Of the société anonyme under the name “Petsiavas N. Société Anonyme” with registered office in Kato Kifissia of Attica (21 Aghion Anargyron St.) who was present with its lawyer Mr. Ath. Tegopoulos (Bar Association No 3725) who was appointed by means of a special power of attorney.

against the Ministers of: 1) Development, 2) Employment and Social Protection, 3) Health and Social Solidarity and 4) Merchant Marine, Aegean and Island Policy, who were present with Sp. Papayiannopoulos, Legal Counsel of the State.

The above petition is introduced to the Plenary Session of the State following the Act of the Chairman of the Council of the State dated November 25, 2008 due to the importance thereof, in accordance with article 14 par. 2(a), articles 20 and 21 of the P.D. 18/1989.

By means of this petition, the applicant seeks the cassation: 1) of the Joint Ministerial Decision No Φ.42000/14734/532/22-7-2008 of the Ministers of Development, Employment and Social Protection, Health and Social Solidarity and Merchant Marine, Aegean and Island Policy and 2) the Act No

Φ.42000/οικ.22876/2369/13-10-2008 of the General Secretary of the Ministry of Employment and Social Protection and any other relevant action or omission of the Administration.

The trial began with the reading of the Mover's Report, the Counsel D. Kyriilopoulos.

Thereafter the Court heard the proxy of the applicant, who orally developed the reasons for cassation raised and requested that the petition is granted, and then the representative of the Ministers, who requested the rejection thereof.

Following the public session, the court met in the courtroom and

After reviewing the relevant documents

It thought in accordance with the Law

1. Whereas for the filing of the petition in question, the lawful surety bond has been deposited (Special surety bond No 857081/2008).

2. Whereas, by means of this petition, the cassation of (a) the Joint Ministerial Decision No Φ42000/14734/532/22-7-2008 of the Ministers of Development, Employment and Social Protection, Health and Social Solidarity and Merchant Marine, Aegean and Island Policy (B 1460) is requested, which defined the procedure and the manner of payment of the amount owed by the pharmaceutical companies to the beneficiaries insurance agencies and the Public Sector Employees Healthcare Organisation (OPAD) in performance of the provisions of article 13, par. 3 of Law 3408/2005 (A' 212) and b) the Act No Φ.42000/οικ.22876/2369/13-10-2008 of the General Secretary of the Ministry of Employment and Social Protection the applicant pharmaceutical company was invited, based on the annual sales it realised in the domestic market, to deposit to the Account for the Improvement of Social Support, the amount of Euro 340,782.36, which corresponds to the payment of an amount owed by it for the years 2006 and 2007, in performance of the above article 13, par. 3 of Law 3408/2005 and of the aforementioned joint Ministerial Decision.

3. Whereas the petition for cassation in question was heard before the Plenary Session of the Court on 9-10-2009. However, before the conclusion of the case, the Mover of the case, Counsel of the Council of the State V. Gratsias deceased. This is why, the petition in question is introduced for anew discussion by means of the Act of the Chairman of the Council of the State dated 29-3-2011, pursuant to article 307 of

the Code of Civil Procedure, which applies *mutatis mutandis*, pursuant to article 40 of the P.D. 18/1989 (A' 8) also in the trials before the Council of the State.

4. Whereas the first act appealed against is regulatory and the direct questioning of its legality falls into the nullifying jurisdiction of the Council of the State. The second act appealed against is personal and therefore, the questioning of its legality generates an administrative dispute as to the merits, whose trial is subject to the jurisdiction of the Three-Member Administrative Court of First Instance. Given however, that the said last act is based on the first one, the Court rules, that for the reasons attributed to the economy of trial, it must judge the case as to the part it concerns the said personal act (compare Council of the State ( $\Sigma\tau E$ ) in Plenary Session Judgment No 668/2012).

5. Whereas the first of the acts appealed against, which as mentioned above, is regulatory, was published in the Government Gazette on 24-7-2008 and the petition for the cassation thereof was filed on 13-11-2008. Given however that the above publication was effected during the judges holiday period, throughout which the deadlines for the exercise of legal remedies and legal benefits are suspended, the petition in question, as to the part turning against this act, has been filed in time on the 59<sup>th</sup> day from the commencement of the Court year 916-9-2008), when the deadline for the filing of a petition for the cassation of the above act, commenced. Furthermore, the petition in question, as to the part turning against the second act appealed against, which, as mentioned above, is personal, is in any case timely, since it was filed on the 31<sup>st</sup> day from the date the said act was issued (13-10-2008).

6. Whereas, in chapter 27 of the Market Regulation No 14/1989 (B' 343), as amended by the provision of article 1 of the Decision No A3/3525/12.12.2005 of the Deputy Minister of Development (B' 1969), it is defined that: "Article 437 1. The highest wholesale price of medicines is the price these are sold to the pharmacists. This price includes the profit of the medicines trader and the obligatory rebates. 2. The Highest Retail price of medicines is determined based on the Wholesale price, adding the lawful profit of the pharmacists and the value Added Tax. 4. The Highest Insurance Price is 96% of the net price of each pharmaceutical product, as defined in article 438, reduced by the percentage of participation of the person insured. Article 438 1. The net price is the wholesale price reduced by the obligatory rebates...". Furthermore, the provision of article 13, par. 3 of Law 3408/2005, as was in force in the relevant period (in this case), it is defined that: "the difference between the highest

insurance price and the net price of each pharmaceutical product, times the quantity of the pharmaceutical product which was proved to have been offered to insured persons of each insurance fund and the Public Sector Insured Employees in the preceding year, as these prices are determined in accordance with the applicable law, is reimbursed by the pharmaceutical companies to each beneficiary insurance fund under the care and responsibility of the latter. By means of the Joint Decision of the Minister of Development and the competent – as the case may be – Minister, the procedure and every special issue and detail required for the reimbursement of the above difference to the beneficiary insurance fund are regulated”.

7. Whereas, the aforementioned provision of article 13, par. 3 of Law 3408/2005, enacted the reimbursement obligation to the insurance funds and to the Public Sector Employees Healthcare Organisation (OPAD) referred to in par. 9, of the amount corresponding to the difference between the highest insurance price and the net price of the pharmaceutical product, times the quantity thereof which was proved to have been offered to insured persons of each insurance fund and the Public Sector Insured Employees in the preceding year. This regulation, justified by the fact that the insurance funds and OPAD reimburse each year, to their largest part, the expenses of pharmaceutical undertakings for the production of pharmaceutical products, sees, as referred to in the justifying report of the law, to the achievement of a rationalised and financial effective management of the resources of the insurance organisations. Moreover, in order to verify the quantity of the pharmaceutical product which was proved to have been offered to insured persons of each insurance fund and the Public Sector Insured Employees in the preceding year, the same as above regulation, grants the authorisation to the regulatory administration, in parallel with the issue of the Joint Ministerial Decision, to establish an objective system for the determination of this quantity which will be binding for all insurance agencies.

8. Whereas, by invocation of the above authorising provision, the Joint Ministerial Decision No Φ. 42000/14734/532/22-7-2008 of the Minister of Development, Employment and Social Protection, the Minister of Health and Social Solidarity and the Minister of Merchant Marine, Aegean and Island Policy, which defined, in performance of the above provision, the procedure and the manner of reimbursement of the above amount owed by the pharmaceutical companies to the beneficiaries insurance agencies and the Public Sector Employees Health Care Organisation. The provision of par. 1a of the above Joint Ministerial Decision,

mathematically specialises the manner of calculation of the difference between the net price and the maximum insurance price of the pharmaceutical product. In particular, the price of the pharmaceutical product, was defined in the amount of Euro 47.67 (Wholesale price €67,96 less the obligatory rebates of Euro 5.29, less the insured person's participation 15 = 47.67), while the maximum insurance price was determined to the amount of €45.76 (Euro 47.67 x 96%) and consequently, the above difference between the net price and the maximum insurance price (rebate) was defined to the amount of Euro 1.9068 (47.67 – 45.76). Moreover, the provision of par. 1b of the above Joint Ministerial Decision defines the sales of pharmaceutical undertakings in the Greek market in 2006 and 2007 (€4,516,181,041.57 and €5,567,200,500.58 respectively) as well as the amounts that the insurance agencies have paid to the pharmaceutical undertakings in order to cover that above expenses during the above two years (€3,218,312,756.71, i.e. a percentage of 71.26% and €3,831,824,232.45, i.e. a percentage of 68.63% respectively).

Finally, the provision of par. 1(c) of the aforementioned Joint Ministerial Decision defines that: "Each pharmaceutical Company, according to the above, calculates the rebate it is obliged to reimburse for its sales in 2006 and 2007 and deposits the resulting amount to the Account for the Improvement of Social Security which is maintained by the General Secretariat of Social Security, through which the beneficiaries organisations and OPAD will claim the amount corresponding to each of them, in accordance with its participation in the total pharmaceutical expenditure".

9. Whereas the provision of article 6 of Law 3768/1999 (A' 273) as was in force in the period in question, it is defined that: "1. A public law legal entity is incorporated under the name "Public Sector Employees Healthcare Organisation (OPAD)" and the object thereof is to organise, monitor and inspect the system for providing healthcare to Public Sector Employees, to improve the quality and effectiveness thereof, to manage and control financing, as well as to duly utilise the resources available. The Organisation is supervised by the Ministry of Health and Welfare and the Ministry of Economics. The Ministry of Health and Welfare supervises the issues that relate to the provision and inspection of health services to the persons insured. The Ministry of Economics supervises the issues concerning the cost of health services, financial management, control and financing of the Organisation. The regulatory acts that concern the Organisation are issued by joint

Ministerial Decisions of the Minister of Health and Welfare and the Minister of Economics. 3...”.

10. Whereas, in the meaning of the aforementioned provisions, pursuant to which the supervision in OPAD for issues that relate, *inter alia*, to the financing of the Organisation is exercised by the by the Minister of Economics, while the regulatory acts that relate to the financing, either concerning the above Organisation, or concerning the said Organisation together with other insurance agencies, must be countersigned by the Minister of economics.

11. Whereas, as mentioned above, the Joint Ministerial Decision No Φ.42000/14734/532/22-7-2008 appealed against defined, in performance of the authorising provision of article 13, par. 3 of Law 3408/2005, the procedure and the manner the pharmaceutical companies would reimburse the beneficiaries insurance organisations and to OPAD with the amount corresponding to the difference between the above insurance price and the net price of the pharmaceutical product, times the quantity thereof which was proved to have been offered to insured persons of each insurance fund and of OPAD in the preceding year. However, the Minister of Economics did not participate in the issue of this regulatory decision, which refers to a matter that relates to the financial aid to OPAD, as required by the provisions of article 6 par. 2 of Law 2768/1999 and article 13 par. 3 of Law 3408/2005. Consequently, the above decision appealed against is not lawful and for this reason which is validly raised with the petition in question, must be annulled, and therefore, the investigation of other reasons for cassation raised against the said decision are inexpedient.

12. Whereas, with the cassation in accordance with the above, of the Joint Ministerial Decision No Φ.42000/14734/532/22-7-2008, the act of the General Secretary of the Minister of Employment and Social Protection No Φ.42000/οικ. 22876/2369/13-10-2008 which was issued in performance of the above Decision, and invited the applicant to deposit to the Account for the Improvement of Social Security the amount of Euro 340,782.36, which corresponds to the amount owed by it for the years 2006 and 2007, in performance of the said Joint Ministerial Decision, lacked its legal grounds and is for this reason subject to cassation.

13. Whereas, in view of the above, the petition in question must be granted.

**FOR THESE REASONS**

The Court grants the petition.

It annuls (a) the Joint Ministerial Decision No Φ.42000/14734/532/22-7-2008 of the Ministers of Development, Employment and Social Protection, Health and Social Solidarity and Merchant Marine, Aegean and Island Policy and b) the Act No Φ.42000/οικ.22876/2369/13-10-2008 of the General Secretary of the Ministry of Employment and Social Protection, in accordance with the contents of the reasons stated above.

It orders the payment of the surety bond and

Sentences the Greek State to pay the court expenses of the applicant, which amount to Euro nine hundred and twenty (920).

The session was held in Athens on May 25, 2012.

The Chairing Vice Chairman

The Secretary

K. Menoudakos

M. Papasaranti

And the Judgment was published in the public session dated November 2, 2012.

The Chairman

The Secretary

K. Menoudakos

M. Papasaranti