

ARTICLE 12

Reintroduction of the reimbursement list of medicinal products and rationalisation of the framework of administration of medicinal products for serious illnesses

1. a. The State, the social security organisations and any entity and branch of insurance of health care beneficiaries approve and pay medical prescriptions only if they contain medicinal products included in a list of reimbursed medicinal products and only for the approved indications as determined in the summary of product characteristics.

b. For the preparation, revision and supplementation of the list there are applied objective criteria that are determined and specified by joint decision of the Ministers of Labour and Social Security, Health and Social Solidarity, and Economy, Competitiveness and Shipping that is published in the Official Gazette and posted in the website of the National Drugs Agency (EOF).

c. The list of clause a is prepared by a Special Committee created by E.O.F. and is approved by joint decision of the Ministers of Labour and Social Security, Health and Social Solidarity, and Economy, Competitiveness and Shipping that is published in the Official Gazette. The list is revised and supplemented at the minimum annually by the same committee and following the same procedure.

d. The Special Committee of clause c is formed into a body by decision of the Minister of Health and Social Solidarity, comprises nine members and consists of one university professor of pharmaceutics (irrespective to the level of the hierarchy), one university professor of medicine (irrespective to the level of the hierarchy), one representative of the EOF (physician or pharmacist) appointed by its Board of Directors, one representative (physician) of the Central Health Board (KE.S.Y.) appointed by decision of its executive committee, one pharmacist with previous service of at least five years in the NHS and of one representative (physician or pharmacist) of IKA-ETAM (Social security funds), one representative of OGA (Social security funds), one representative of the OPAD (Social security funds), and one representative of the OAEE appointed by decision of their Boards of Directors. Accordingly for each member a substitute is appointed. By the decision of formation of the committee into a body there are designated the chairman of the committee and his deputy among the above-mentioned University

Professors and the secretary of the committee with his deputy among the employees of EOF. The compensation of the members of the special committee and of the secretary which, in accordance with the existing provisions, charges the budget of EOF as well as any other procedural detail is specified by joint decision of the Ministers of Health and Social Solidarity and Finance.

e. Within 15 (fifteen) days from the publication of the Joint Ministerial Decision of clause c hereof, the interested manufacturers and importers of medicinal products which have not been included in the list, may submit an application for their inclusion before the special committee. The application is accompanied by the data supporting it and the applicants are invited to develop their arguments orally before the special committee. Within 30 (thirty) days from the submission of the application, the special committee, provided, based on the objective criteria of par. 2, it considers the request as well founded, prepares a supplementary list that is approved in the manner specified in clause c hereof.

f. The administration of a medicinal product that is not included in the list is approved for the period of patient's treatment only in exceptional cases by the resolution (issued within ten days from the submission of the relative request) of the Board of Directors of the Insurance Entity or by its legally authorized Body. The resolution is issued upon justified request of the treating physician and following the opinion of the special committee of clause c of this paragraph of this article. .

g. As from the publication of the catalogue of the clause a' of this paragraph of this law, the paragraph 1 of the article 1 of the l. 3457/2006 is abolished. The provisions of article 19 of l. 1902/1990 (Off. Gazette 138 A') and of article 31 of L. 2166 (Off. Gazette 137 A') as well as the Ministerial Decisions issued by authorisation thereof, remain in force. Also, the provisions providing for reimbursement by the State and the entities and branches of health insurance, the expense for the medicinal products administered to economically weak and uninsured persons continue to apply.

2. a. Outpatients insured with the State and the social security entities or are entitled to health care under special provisions, may obtain both from the pharmacies of state hospitals and from private pharmacies, without participation in the expense, medicinal

products for the treatment of serious illnesses that have an authorisation only for hospital use or an authorisation for beginning of administration in the hospital and follow-up by a specialised physician.

b. The private pharmacies obtain the medicinal products administered as per clause a of this paragraph under the same terms and at the same price at which they are obtained by the pharmacies of state hospitals.

c. A Joint Ministerial Decision of the Ministers of Health and Social Solidarity and Labour and Social Security and Economy, Competitiveness and Shipping published in the Official Gazette approves, following the proposal of EOF, a list of the medicinal products for the treatment of serious illnesses of par. 2 of this article. The said list is revised and supplemented at the minimum annually following the same procedure. For the determination of cost, the wholesale price of the medicinal products and their packaging in conjunction with the daily treatment cost are taken into consideration. The manner of configuration of the price with which they are marketed to the hospitals or the private pharmacies is determined by a Market Decree.

d. The list of medicinal products of paragraph 2 of the present article is approved provided that they are necessarily included in the reimbursement list of the preceding paragraph of this article. The above prerequisite is not required for the period until the issuance of the first reimbursement list of paragraph (1) of this article of this law, for which period and pending the issuance of the list in implementation of this article the list of medicinal products of the Joint Ministerial Decision DYG3a/G.P.151509/19-12-2008 (Off. Gazette 2717/31-12-2008, issue B) continues to apply.

e. Article 26 of L. 2072/1992, as substituted, is abolished as from the publication of the Joint Ministerial Decision of the clause c' of the paragraph 2 of the present article .