

Provisions concerning medicinal products

1. The provision of paragraph 7 of Section H of article 21 of Law 4052/2012 (A' 41) as amended and in force is substituted as follows”.

“b. For the preparation, revision and supplementation of the list, a ranking system of the medicinal products is applied, according to the Anatomic Therapeutic Chemical Classification – ATC system of the World Health Organisation (WHO) and a system of reference prices (R.P.) is introduced per therapeutic category of medicinal products. The Reference Price is the lowest daily treatment cost among the medicinal products of each therapeutic category. In parallel, safety and efficiency are examined and the reimbursed indications, strength and package are selected per medicinal product. By virtue of the decision of the Minister of Health which is published in the Government Gazette and posted at EOF’s website, the manner for the drawing up of the therapeutic categories and the determination of the reference prices per therapeutic category as well as the procedures for the revision and supplementation of the list are particularised, as well as the reimbursed indications, strength and package are selected per medicinal product. The Social Insurance Agencies reimburse the cost of on-patent medicinal products as regards the active substance which have obtained a marketing authorisation in Greece after 1.1.2012, if such cost is reimbursed by Social Insurance Agencies in the 2/3 of the Member-States of the European Union or in at least 12 Member-States of the European Union, whose Social Insurance Agencies reimburse the cost of these medicinal products following an evaluation from valid Health technology evaluation organisations, provided that the Directive 89/105/EC is fully complied with regarding transparency. By virtue of the decision of the Ministry of Health, medicinal products which are characterised as necessary for the coverage of danger against human life or orphan drugs may be excluded, only when they are covered by international clinical protocols”.

2. Case (c) of paragraph 1 of article 12 of law 3816/2010 9A’ 6) as amended and in force is substituted as follows:

“c. The list set out in paragraph a is prepared by the Special Committee formed within EOF and it is approved by the decision of the Minister of Health, which is published

in the Government Gazette. The list is revised and supplemented at least once a year by the same Committee and with the same procedure. Any corrections that result in case errors are corrected in the Positive Prescribing List, if they are approved by the Special Committee for the approval of the positive list and after the consent of the Directorate of Medicinal Products and Pharmacies of the Ministry of Health, are forwarded to HDIKA for the relevant actions thereof.

Athens 27.2.2014

THE MINISTERS

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