Article 47
Coverage of Medicinal Products outside the scope of the approved indications

At the end of case (a) of par. 1 of article 12 of Law 381/2010 (A' 6) as currently in force, the following clause is added:
"Medicinal products of the positive list which are prescribed and reimbursed by EOPYY for indications, combinations and dosage schemes not included in the approved indications, as these are defined in the abstract of the characteristics of the pharmaceutical product, only in the case they are included in therapeutic protocols, which are in line and rely upon respective international guidelines, have been suggested by the competent scientific societies any have been approved by the KESY. By decision of the Minister of Health, the terms and conditions for their integration in the e-prescribing system are defined, which is a necessary condition for the application of the above. Medicinal products outside the scope of the approved indications can be reimbursed by EOPYY only in exceptional cases and in accordance with the references of international literature and documented on an individual basis, upon the filing of a documented request by the healthcare agencies. The terms and conditions for the application of the above are regulated by decision of the Minister of Health".

7a) Disclosure Obligation
Each Pharmaceutical Company is obliged to disclose by name at its website and at the designated website of EOF, not later than six months from the end of each calendar year, any benefit it grants to third Healthcare Professionals and Scientific Healthcare Agencies (Scientific Societies), including but not limited to, grants, donations, entry cost in conferences and events for scientific information of the medical community, as these are specifically defined in the circulars of EOF issued from time to time, travelling and accommodation expenses as well as any other benefit based on an agreement or at its free will, in relation to the promotion of the prescribed medicinal products. Benefits that concern Research and Development activities, as well as non-invasive clinical trials (with or without the application of a medicinal product) will be cumulatively disclosed by each pharmaceutical company. Cost for market rese4arch, meals and drinks, as well as objects of minor value for medical application and training are expressly excluded from the disclosure obligation, which are directly associated with the conduct of the daily medical practice of Healthcare Professionals and Scientific Societies, pursuant to article 126, par. 1 of the Ministerial Decision No ΔΥΓ3α/ΗΠ 3221/2013 (Β1049). Minor value is the value of every object which does not exceed in total the amount of Euro fifteen (€15), including VAT. According to the provisions of the Joint Ministerial Decision No Υ6α/28403/01/27.5.2002 of the Minister of Finance and Economics, the Minister of Development and the Minister of Health and Welfare, which was issued by authorisation of par. 1 of article 49 of Law 2519/1997 "Development and Modernization of the National Health System, organising of healthcare services, provisions for medicinal products", as and currently in force by the Joint Ministerial Decision No Υ6α/οικ. 121863/11.12.2002, the costs defined therein are deducted from the gross income of pharmaceutical companies.
b. Sanctions
The supervision for the observance hereof lies with the competencies of the National Organisation for Medicines. The perpetrators are levied with administrative sanctions ranging from Euro 30,000 to Euro 100,00 in favour of the State.