

Ministerial Decision No. ΔΥΓ3(α)/οικ. ΓΥ/154

(5)

Proprietary medicinal products outside approved indications (off-label)

THE MINISTER OF HEALTH AND SOCIAL SOLIDARITY

Having regard to:

The provisions of:

1. Article 8 para 4 of Law 3457/2006 (Government Gazette A 93);
2. Presidential Decree 121/2008 (Government Gazette 183/A/2008) “Obligations of social security funds, attending and controlling doctors and pharmacists, and related sanctions”;
3. Joint Ministerial Decision Φ.90380/25916/3294 (Government Gazette 2456/B/2011) “Uniform Regulation of Healthcare Benefits of the National Organisation for the provision of Health Services (EOPYY)”;
4. the fact that the government budget shall not incur any expenditure as a result of this Decision;

We decide as follows:

1. To prohibit, under the responsibility of the attending doctor, the prescription of pharmaceutical products outside the approved indications and dosages specified in the Summary of Product Characteristics (SPC).

The prohibition shall apply to prescriptions for inpatients and outpatients alike..

2. EOPYY and the social security funds shall not reimburse prescriptions for medicinal products outside the approved indications and dosages.
3. In exceptional circumstances and in line with international literature, EOPYY or other social security funds may request a derogation by submitting a fully reasoned application addressed an ad hoc committee to be set up within EOF, whereupon the positive opinion of the aforementioned committee is a prerequisite for the medicinal products to dispensed and reimbursed.

We order that this Decision be published in the Government Gazette.

Athens, 29 February 2012

THE MINISTER

ANDREAS LOVERDOS