HealthCare Newsletter

"Off-label" reimbursement of medicinal products

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The controversial question regarding "off-label" use of medicinal products has been recently tackled by the Greek legislator.

Article 47 of Law 4316/2014 entitles the National Organization for Healthcare Services ("EOPII") to reimburse:

a. medicinal products for indications, dosages and combinations not in accordance with the summary of product characteristics ("off-label" use) subject to the following preconditions.

   The "off-label" indications, dosages and combinations should be:
   i. incorporated into therapeutic protocols which comply with international guidelines
   ii. recommended by the competent scientific societies and
   iii. approved by the National Healthcare Council ("KESI")

b. medicinal products for "off-label" use under exceptional circumstances, following a well-substantiated individual request of the healthcare practitioner and subject to compliance with references of international bibliography.

The implementation of this new rule will become possible after the issuance of a relevant ministerial decision by the Minister of Health, which will determine the necessary practical details for the application thereof.

However, the level of compatibility of above provision with EU pharmaceutical law is rather questionable. In the absence of a judgment of the Court of Justice of the EU on the permissibility of "off-label" use so far, there are quite a few arguments challenging the conformity of this regulatory approach with the Market Authorization rules set by the provisions of Directive 2001/83/EC.

Last, from a competition law perspective, the new provision could potentially raise issues of relevant product market definition, which is currently based on the

Anatomical Therapeutic Chemical Classification System ("ATC"), taking into account therapeutic indications and molecule.

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