

New provisions of Law 4472/2017 regarding the Greek Healthcare Sector

Law 4472/2017 introduces, inter alia, major changes in Greek healthcare system, mainly by instituting a new public authority with many critical responsibilities related to public tenders. Several provisions related to the pharmaceutical/medical device industry are also included.

General

On May 19th, Law 4472/2017 was published which introduces multiple changes to the healthcare sector. This Law, in articles 21 to 35, provides for a new authority named National Central Authority of Health Procurements (NCAHP or EKAPY as per its Greek initials) that effectively replaces the Health Procurements Committee (HPC or EPY as per its Greek initials). Moreover, in articles 85 to 95 certain critical matters are redefined regarding the supervision of private primary health services, the pricing of non-prescription medicines (OTC's), rebates, positive list, HCP's limitations to medicine's prescription and others.

The National Central Authority of Health Procurements

The new provisions were adopted in view of the Greek government's compliance to the obligations stemming from its ongoing bailout program. These obligations are mostly related to the rationalization of public expenses related to public health procurement through a smarter and better organized division, which is no longer assigned to the HPC and Hospitals, but to a Central Authority (NCAHP/EKAPY). The main points described in articles 21-35 are the following:

- The National Centralized Authority of Health Procurements replaces the Health Procurements Committee in its competencies.
- The National Centralized Authority of Health Procurements is organized in eleven Registries.
- The National Centralized Authority of Health Procurements collects the supply needs of the entities and strategically plans their coverage.
- The National Centralized Authority of Health Procurements procures all public tenders of health supplies (unless their annual budget runs under € 60,000 or they are co-funded by European Programs).

Private Primary Healthcare Services

According to article 85 of L. 4472/2017, the private entities which provide primary Healthcare Services are exempted from the obligation of issuance of the previously required operation certificate and the respective administrative sanctions.

Furthermore, the new Law redefines the pricing procedure of OTCs and provides for the establishment of a relative Price Observatory for this type of medicines providing at the same time strict sanctions in case of no compliance.



Rebates

Article 87 of the new Law, introduces a new 25% rebate for the incorporation of New Products (which are still in their data protection period) in the Positive List after the Law's issuance. It also reforms the calculation method of the amount of rebate from the MAH's to the Public Insurance Entities and E.O.P.Y.Y. by providing for a new, more complicated algorithm. Pharmaceutical companies are also obliged to provide discounts to pharmacies for particular products under specific circumstances.

Positive List

The prerequisites for the inclusion of a product in the list of medicines which are reimbursed by the State are redefined. Article 89 abolishes the Second-degree Committee, whose work will be assumed by the special Committee that issues the positive list.

Merger of MAHs and manufacturers/ Distribution of pharmaceutical products

Further changes are foreseen in articles 90 and 91 regarding the procedure and prerequisites for maintaining an operation and manufacturing license in case of mergers as well as regarding the physical distribution of pharmaceutical products and the liability of the MAH during their transportation.

Limitation in Doctors Prescriptions

The new Law provides the Health Minister with the authorization to issue a Decision determining the financial limitations, targets

and means of control regarding the prescription writing (article 93).

Pharmaceutical Wholesalers

Among other provisions related to wholesalers, article 94 provides for new regulations on their auxiliary facilities.

EOPYY's Negotiation Committee

New rules are also introduced regarding the procedure before the Negotiation Committee of EOPYY and the liability of its members. From the issuance of the new Law, the participation of the invited pharmaceutical company to the negotiation is obligatory, otherwise, serious sanctions may be imposed.

Medical Devices

June 1st, 2017 is defined as the new enforcement date of the new pricing system. According to the new system, the three lower European prices will be taken into account in order for a medical device to obtain a price through the competent state authority.

Conclusion

All in all, careful consideration is in order vis-à-vis the new Law, since it contains numerous amendments and new regulations which cover a wide range of matters pertaining to the industry.



KYRIAKIDES GEORGOPOULOS
Law Firm

Contact

For any further comment or query, please contact the KG lawyer you are in contact with or the Pharmaceutical Law practice team.

Kyriakides Irene

Partner

i.kyriakides@kglawfirm.gr

Charalabopoulou Nefelie

Senior Associate

n.charalabopoulou@kglawfirm.gr

Main (Athens) Offices

28, Dimitriou Soutsou str.

115 21, Athens

Greece

Tel: +30 210 8171500

Fax: +30 210 68 56 657/8

Thessaloniki Branch

17, Ethnikis Antistaseos str.

551 34, Thessaloniki

Greece

Tel: +30 2310 441552

www.kglawfirm.gr

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