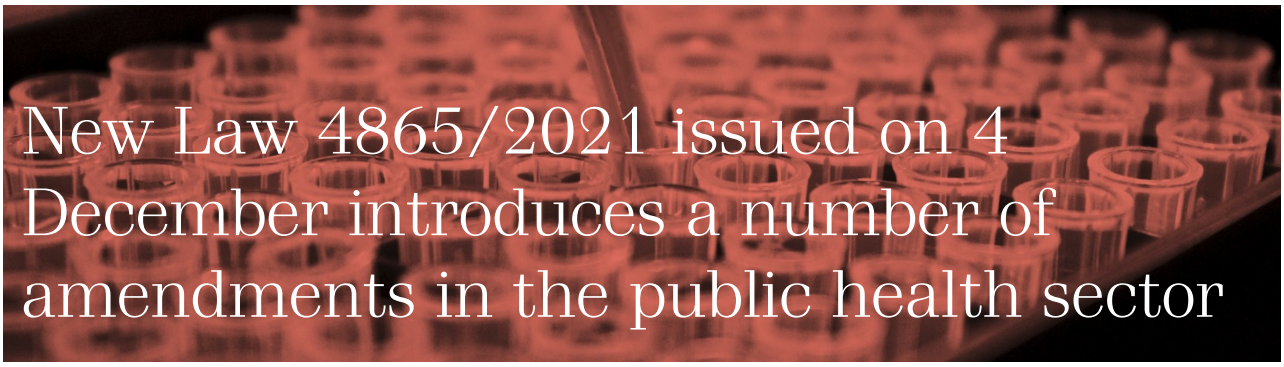

New Law 4865/2021 issued on 4 December introduces a number of amendments in the public health sector

The key changes/amendments introduced by new Law 4865/2021 may be summarised as follows:

I. Establishment of the new private law entity under the name

"National Centralised Health Procurement Authority" (EKAPY, as per its Greek abbreviation) in replacement and abolition of the former EKAPY, which had been established as a public law entity. The new regime aims to create a more flexible and efficient health procurement system.

New Law 4865/2021 redefines EKAPY's responsibilities. More specifically, as of its establishment, EKAPY is competent, *inter alia,* for (a) centralised coordinating and undertaking receipt, storage and distribution of health products, materials and services, (b) monitoring and controlling the consumption of consumables of public health services, (c) planning and conducting public tenders for the procurement of products, materials and health services in the public sector and (d) creating, operating and regularly updating a number of Electronic Registries falling under its remit related to health supplies, as specifically provided in par. 2 of Article 4 of said Law, including the Registry of Products, Services and Suppliers, the Central Procurement Registry, the Cost and Consumption Registry, as well as the Technical Specifications Registry. In addition, EKAPY is competent for preparing the Central Procurement Strategy (CPS) of health products and services every three (3) years as well as to revise such CPS whenever required.

The anticipated benefits from the establishment of EKAPY as a private law entity and the responsibilities to be undertaken by the latter are multiple. *Grosso modo,* through the CPS undertaken by EKAPY, procurement procedures shall be accelerated, payment delays as well as overdue obligations are expected to be reduced and the operating costs of hospital units shall be streamlined. Lastly, through the reduction of costs and administrative burden, resources shall be saved for further strengthening of public health structures.

II. Amendments regarding pharmaceutical expenditure.

Under the new Law, by a decision of the Minister of Health, the annual budget for pharmaceutical expenditure may be set at a drug level or on the basis of active substance (ATC 5), therapeutic category (ATC4), medicines i) of high cost, or ii) within their data protection period, or iii) after expiry of their data protection period, or iv) without data protection period. The foregoing provision may be applied especially in cases where a number of new medicines in specific therapeutic categories is introduced. In such cases, the individual budget objective shall also be taken into account for the determination of the excess of EOPYY's pharmaceutical expenditure of as well as for allotting the excess per pharmaceutical company per Marketing Authorisation Holder (MAH).

III. Revisions or medicines' prices.

Under Article 40 of new Law 4865/2021, by a decision of the Minister of Health, it may be decided that, in exceptional cases and for restraining pharmaceutical expenditure, the next complete revision of medicines' prices may be effected sooner than originally provided; the

foregoing decision shall also define the price reduction limit. Similarly, by virtue a decision of the Minister of Health, incentives may be introduced to move medicines from the positive list of reimbursed medicines to the negative list (i.e. of non-reimbursed medicines), as well as different pricing criteria depending on their inclusion in the positive or the negative list. In case of generic medicines, the new prices are published within thirty (30) days from MAH's application.

IV. Provisions related to EOPYY's Negotiation Committee.

Under Article 41 of new Law 4865/2021, by a decision of the Minister of Health, EOPYY's Negotiation Committee, negotiation procedure and operation, as well as the criteria for negotiation are determined, including, in particular, clawback and rebates, sales volume and ex-factory prices in other EU countries, especially when said are below the respective prices in Greece and the medicine in question is under protection, as well as the date of expiry of its protection period. The foregoing decision may also provide in detail the criteria for determining reimbursement price per medicine category depending on their distinction into reference medicines or generics, determine the extent of participation of the insured per drug category and specify how price differential per category between reimbursement and retail price shall be covered.

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