



## Recent developments in the healthcare sector

Significant changes in the public and private healthcare sector are introduced, leading to amendments in the employment of NHS doctors, the system for the provision of palliative care, imposition of VAT on Covid-19 vaccines, as well as extension of the Medical Device Regulations.

### 1. Employment of NHS doctors in the private sector

By way of exception to the general prohibition of employment of NHS HCPs in the private sector, article 10 of Greek Law 4999/2022, entered into force on 7 December amended article 11 of Greek Law 2889/2001 governing the employment status of NHS HCPs. More specifically, under the foregoing amendment, the operation of private practice or the provision of healthcare services under any relationship, including that of a consultant, in a private clinic or a private diagnostic or therapeutic laboratory and in general in any type of private healthcare units up to twice per week, has been permitted, subject to the Hospital's Administrator approval in this respect and following the HCPs in question request. A prerequisite for the approval to be granted is the requesting HCPs' participation in the operation of the hospital outside regular hours,

including the all-day operation of the hospital and on-call shifts, at least eight (8) times per month, of which at least four (4) shall relate to the daily operation of the hospital, beyond regular hours. Cases undergoing diagnostic procedures or paraclinical examinations or surgical or interventional procedures performed outside the hospital per week may not exceed one third (1/3) of the number of corresponding procedures cumulatively performed during regular hours and full-day operation of the hospital by the same HCP.

Violation of the foregoing provisions in terms of the limitations entered into force so as to safeguard that the right given to HCPs, as per above, shall not be abusively used to the detriment of NHS hospitals and patients is subject to administrative sanctions including the immediate revocation of the approval granted to provide healthcare services in the private sector and the immediate

revocation of the licence to operate a private practice. In addition, the HCP shall be prevented from submitting a request, as per above, for a period of six (6) months; recurrent violation of the foregoing limitations may lead to an extension of the aforesaid period up to two (2) years or to a definite loss of the right to file a request for employment in the private sector.

Similarly, members of the teaching and research academic staff or the laboratory teaching staff of the Universities (AEI, as per their Greek acronym), who are physicians employed by university clinics or university laboratories or work at units of Departments or Schools of Health Sciences of AEI, are entitled to provide services to private clinics, private diagnostic or therapeutic laboratories and in general to private healthcare units, subject to a permission granted by the Senate of the competent University.

## **2. Establishment of an integrated system for the provision of palliative care**

By virtue of the provisions of Chapter B of Greek law 5007/2022, improvement of the quality of life of patients suffering from a life-threatening disease or a chronic progressive disease, by setting up the regulatory framework for the establishment and operation of an integrated and autonomous system of providing palliative care, which, in combination with the other existing NHS structures, will focus on and serve the specialised needs of these patients and their families, is entered into force. Palliative care shall be provided at primary, secondary and tertiary level, depending on the needs of the patients in need, and is divided into general and

specialised palliative care. As general palliative care is defined care provided by HCPs who undertake the treatment and care of patients with life-threatening illnesses. General palliative care includes the assessment and management of symptoms, communication with the patient and his/her family in terms of the diagnosis and prognosis as well as the collaboration or referral of the patient in question to specialised palliative care services. Specialised palliative care means care provided by a multidisciplinary team, which consists of a physician, a nurse, a social worker, a psychologist, an occupational therapist, a physiotherapist, a dietitian, a speech therapist, a pharmacist, and other therapists with certified knowledge in palliative care. The work of the aforesaid interdisciplinary team can be supported by specially trained volunteers.

Palliative care services shall be provided in Palliative Care Facilities either as public or private entities.

In the context of the National Action Plan for Public Health, the Central Health Council shall prepare, following a proposal from the National Committee for Development of Palliative Care, and approval by the Minister of Health, the National Action Plan for the Development of Palliative Care (the "ESDAAF"). The ESDAAF shall constitute the roadmap for the implementation of a coherent policy for the provision of holistic palliative care services with a five-year horizon and shall include: (i) the strategic and operational policy objectives for the development of palliative care, as well as quantitative and qualitative indicators for measuring their achievement, (ii) the set of actions for the development of palliative care, the priority axes in which they shall be

included, as well as the budget, financing and timetable for their implementation, (iii) the framework for the organisation of the provision of palliative care services and the manner of coordination and cooperation between the public and private bodies active in the development of palliative care and the provision of palliative care services, (iv) the quantitative and qualitative assessment of palliative care services provided in the country, (v) the quantitative and qualitative assessment of the provision of palliative care services in the interconnected palliative care service provision structures and (iv) the pilot actions to be implemented during its implementation.

### **3. Imposition of VAT from 1.1.2023 on Covid-19 vaccines, rapid diagnostic tests, PCR diagnostic tests and other diagnostic tests and services related to the above**

AADE Circular No. E. 2002/2020 and the provisions of article 73 of Law 4764/2020 had added a new paragraph 1A to article 21 of the VAT Code (L. 2859/2000) and provided for the application of a zero VAT rate to import and delivery of goods directly related to the treatment of the Covid-19 disease (vaccines and in vitro diagnostic products). The same rate was applied to services closely related to the goods of the previous paragraph. By virtue of these provisions, the Greek legislator made use of the possibility given to the EU Member States to apply a zero rate to various items related to the combat of Covid-19 as well as to related services, in accordance with article 129a of Directive 2006/112 /EC, as added by Article 1 of Directive (EU) 2020/2020. The above

provisions of paragraph 1A of article 21 of the VAT Code, which came into force on 23.12.2020, were to be applied until 31.12.2022. As of 01.01.2023, vaccines, rapid diagnostic tests, PCR diagnostic tests and other diagnostic tests are henceforth subject to VAT of 6%. The same rate shall apply to the price charged by pharmacies to consumers who, when purchasing the diagnostic tests, request from the pharmacist himself to perform the test. It should be reminded that diagnostic tests (either rapid or PCR) performed by public or private healthcare units and laboratories are still not subject to VAT.

### **4. Proposal for the extension of Medical Device Regulations 2017/745 (MDR)**

The European Commission has issued on 6 January 2023 a legislative proposal for extending the transition period for legacy devices (i.e. those covered by a certificate or declaration of conformity issued under Council Directives 90/385/EEC or 93/42/EEC before 26 May 2021 that are now regulated under the MDR provisions). Provided that the proposal enters into force and subject to the conditions stipulated by the proposal with regard to the several cumulative conditions for the application of the extended transition period, devices that will benefit from the extension of their certificates and thus, may be placed on the market or put into service until (i) 31 December 2027 for higher risk devices (class III and class IIb implantable devices except certain devices for which the MDR provides exemptions, given that these devices are considered to be based on well-established technologies) and until 31 December 2028 for medium and

lower risk devices (other class IIb devices and class IIa, class Im, Is and Ir devices). Class III custom-made implantable devices benefit from an extension to 26 May 2026.

## 5. Upcoming developments

Around mid-December, the president of the National Central Authority for Health Procurement (EKAPY), Aris Apostolou, during his speech in the course of the Panhellenic Conference on Health Economics and Policies for 2022, announced significant amendments related to the procurement and supply of medicines by the NHS hospitals. More specifically, EKAPY is intended to serve as the central purchaser of medicines for all NHS hospitals while the supply of medicines shall be effected electronically

through a special platform. The aim of the foregoing legislative reform is to monitor consumption of medicines and limit overdue debts, since payment of invoices shall take place within ninety (90) days. The new procurement system was expected to enter into force on 01.01.2023; however, due to various inadequacies, the contemplated legislative provision was held back by the Ministry of Finance for further review and is expected to come into effect within January and thus, the new system shall become operational in early February 2023.

## Contact us



**Nefelie Charalabopoulou**  
Partner

[n.charalabopoulou@zeya.com](mailto:n.charalabopoulou@zeya.com)



**Natalia Kapsi**  
Senior Associate

[n.kapsi@zeya.com](mailto:n.kapsi@zeya.com)

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280 Kifissias Ave., 152 32 Halandri, Athens, Greece  
[newsletters@zeya.com](mailto:newsletters@zeya.com)  
Tel.: (+30) 210 696.70.00 | Fax: (+30) 210 699.46.40

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