

Emergency Measures in the Healthcare and Life Sciences Sector to address Covid-19

In response to the growing complexity and unpredictability of the Covid-19 pandemic worldwide, the Greek Government has adopted a set of measures to face, to the maximum and possible extent, this unprecedented crisis.

In particular, with regard to the healthcare and life sciences sector, the Greek Government, acknowledging the insufficient means available, not only in terms of personnel but also in terms of life-saving equipment and other essential supplies to prevent the spread of the virus and take care of the patients, has adopted a variety of measures in an attempt to tackle the pertinent crisis.

In particular, the following measures have been enacted to date:

A. Legislative Act issued on February 25th, 2020

i. Compulsory disposal of facilities

By their joint decision, the Ministers of Finance and Health may order, for a period of four (4) months as of the publication of this Act and provided that there is still an imminent risk for the emergence as well as the spread of coronavirus, the compulsory contribution to the public sector of private hospitals and clinics, Intensive Care Unit (ICU) beds, hotels, private housing services facilities as well as other public properties or properties belonging to public entities, so as to meet public health needs related to the treatment of patients infected by Covid-19, on condition that said needs cannot be differently addressed. The aforementioned Joint Ministerial Decision shall define the specific public health needs, the quantities of materials and facilities to be bound, the period for which said shall remain bound, the manner of compensation for the materials or facilities disposed for this purpose as well as any relevant details for the implementation of this provision.

B. Legislative Act issued on March 11th, 2020

i. Contribution of medical equipment

Medical equipment may be contributed from one hospital or healthcare service provider to another, even if said fall under the competence of different Health Districts, in order to respond to the urgent needs resulting from the emerging outbreak and spread of Covid-19 coronavirus, for one semester at most and with a possibility to extend said period for another six (6) months. The same measure may also apply to hospitals or healthcare service providers belonging to the same Health Districts.

C. Legislative Act issued on March 14th, 2020

i. Emergency measures to ensure the adequacy of personal protective equipment and personal hygiene

The Greek Government has adopted a set of extraordinary measures to ensure the adequacy of personal protective equipment and personal hygiene. More specifically, according to the said Act, companies active in the chain of production, import, marketing, sale, brokerage, movement and distribution of medicinal products and personal protective equipment and personal hygiene products in the Greek territory shall submit to the competent authority every two (2) days, a report as to their stock in: (a) surgical masks; (b) antiseptic solutions; and (c) antiseptic wipes.

ii. Requisition of goods, consumable and non-consumable

The Greek Government, taking advantage of its right to requisite property for the purpose of facing an immediate social emergency that may endanger public order or health (Art 18 par 3 of the Greek Constitution), has proceeded to reinstate its option to confiscate goods, consumable and non-consumable, that belong to individuals or legal entities and fall within the meaning of special hospital equipment, personal protective equipment and medicines for a period of six (6) months. In the scope of special hospital equipment fall: respirators, hospital beds, standard bed equipment, vital signs monitors, closed suction systems and necessary medical devices relating to the ventilator function. Personal protective equipment is defined as: masks of all kinds, personal protective equipment and sanitary clothing.

D. Legislative Act issued on March 20th , 2020

i. Maximum quantity of goods sold for personal hygiene and protection

A maximum amount of three (3) units may be imposed by suppliers on the retail sale regarding products of personal protection and hygiene, e.g. antiseptics, masks, disinfectants for the next six (6) months provided there is still a risk of Covid-19 spreading.

ii. Restriction on sampling cosmetics

No sampling of cosmetics may be effected to consumers and any such sampling products must be removed from all retail outlets for a period not exceeding six (6) months as of the date of entry into force of this Act.

iii. Maximum profit margin

A maximum profit margin is set at that which was effective on February 1st 2020 for products which are necessary for the health, nutrition, transportation and security of the consumers, especially pharmaceuticals and medical devices such as surgery masks, antiseptics etc.

iv. E-prescriptions

For a period of two (2) months as of the date of entry into force of this Act, given the threat of further spread of Covid-19 and aiming to limit physical contact between patients and HCPs, by way of derogation from all applicable provisions on e-prescriptions, all medical prescriptions may be obtained through the electronic portal <https://www.e-syntagografisi.gr/p-rv/p> using the taxisnet codes.

v. Primary care at home through mobile units

Mobile units are introduced for the purpose of offering primary care services to patients at home and sampling for Covid-19.

vi. Sending of pharmaceutical products to patients via courier

The option of sending pharmaceutical products directly at patients' home by EOPYY's pharmacies via courier services is introduced for the next four (4) months provided there is still a risk of Covid-19 spreading. The exact procedure to be followed will be set out in a decision of EOPYY.

vii. Suspension of execution of public procurement contracts

According to article 60 of this Act, the competent Minister, as the case may be, has been given the option to issue a ministerial decision with the below measures, which can have duration up to six (6) months as from the 20th March 2020 and in particular:

a) suspension of tendering procedures, b) extension of the submission of the participation petitions or the tender offers in cases whereby the tender has already been published, c) suspension of every time limit regarding the public procurement regardless of the status they are in (award or execution of the contract) and d) extension for all types of contractual deadlines.

In addition to the aforementioned legislative measures, the National Organization for the Provision of Healthcare Services (EOPYY) has adopted certain preventive measures for the safety of the population. More specifically:

- HCPs are given the opportunity to issue repeated medical prescriptions until 30.06.2020 for vulnerable groups of the population.
- Patients receiving High Cost Drugs (CVD) from EOPYY pharmacies and belonging to vulnerable groups can appoint a proxy to receive their medicines with a simple solemn declaration (without certification of their signature).
- Scheduled delivery of High Cost Drugs (by appointment) enters into force at the EOPYY central pharmacy in Maroussi and thereafter, the service will be available at all EOPYY's pharmacies.
- The possibility of online submission for the execution of electronic advice on special treatment provided by certified (non-contracted) therapists through the EOPYY's online applications at no cost for the insured is set forth.
- The date of submission, for February, of all healthcare service providers contracted with EOPYY, is extended until 31.03.2020.

Also, the **National Organisation for Medicines (EOF)** has decided on:

- a. The temporary suspension of all Good Manufacturing Practice (GMP), Good Distribution Practice (GDP) as well as on-site market inspections, in the context of implementation of measures taken to limit Covid-19 spreading. In cases where suspension is not possible, taking into account the nature and necessity of the inspection and upon assessment of the associated risk, on-the-spot inspections/audits related to serious complaints or other emergencies shall be carried out.

- b. The temporary prohibition of parallel exports and intra-Community movement of certain medicinal products whose sufficiency is crucial for the treatment of patients infected by Covid-19 or suffering from other respiratory infections.

Lastly, upon consultation between the Ministry of Health and the Governor of the Independent Authority for Public Revenue (AADE, as per its Greek abbreviation), the amount of 122.6 tones of ethyl alcohol that has been seized in the past years by AADE, shall be used for the production of antiseptics to be made available to Hospitals, Health Centers and healthcare units of the country in order to tackle the existing and identified deficiencies.

The list measures adopted, as provided hereinabove, is dynamic and the Greek Government, based on the constantly updated scientific data as to the spread of the virus may proceed to additional enactments to sustain the battle against Covid-19.

On a last note the **European Commission** proposed a 1 year extension to **the Medical Device Regulation 2017/745** transition deadline. Commission spokesperson, Stefan De Keersmaecker, commented that the Commission is still working on the proposal, but plans to move to the European Council and then the European Parliament in early April. Additionally, MedTechEurope, supported by the UK ABHI and Germany's BVMed requested as well an extension, until 6-months after the Corona virus Pandemic is declared over by the WHO.

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