

LIFE SCIENCES & HEALTHCARE BRIEFING: Special Edition

Latest Developments in Life Sciences & Healthcare Legislation: Urgent Measures Relating to Covid-19 Pandemic

This Briefing provides an overview of changes introduced to life sciences and healthcare law by new legislation arising out of the Covid-19 pandemic

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A. Prohibition of Profit Margin Increases for Pharmaceuticals and Personal Hygiene Products

1. Articles 21 and 22 of the Act of Legislative Content of 20 March 2020 (Official Government's Gazette A/68) prohibit companies from benefiting from the sale of goods or services essential for the health, nutrition, movement and safety of consumers, including:
 - a. medicinal products;
 - b. personal protective equipment; and
 - c. personal hygiene products, such as surgical masks, antiseptic liquids and other disinfectants.
2. The gross profit margin for these products cannot be greater than they were before 1 February 2020. Consumers can now submit complaints to the authorities and, depending on the gravity of the violation, fines from €1,000 to €1,000,000 may be imposed.

B. Obligation of Pharmaceutical and Healthcare Companies to Declare their Stocks in Surgical Masks, Antiseptic Solutions and Antiseptic Wipes

1. Article 2 of the Act of Legislative Content of 14 March 2020 (Official Government's Gazette A/64) stipulates that within two days from its entry into force, ie by 16 March 2020, companies active in the chain of production, import, marketing, sale, brokerage, trading and distribution of medicinal products, personal protective equipment and personal hygiene products within the Greek territory must submit a list of the stock they hold in the following items electronically to the Ministry of Development and Investment:
 - a. surgical masks;
 - b. antiseptic solutions; and

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- c. antiseptic wipes.
2. Companies should use their passwords for the General Registry (GEMI) platform and non-declaration or false declaration could lead to seizure of products and fines from €1,000 to €100,000 depending on the gravity of the violation.

C. Special Purpose Leave for Employees in Pharmaceutical and Paramedical Companies

1. Article 14 of the Act of Legislative Content of 14 March provides that a Special Purpose Leave may be granted to parents who work in companies dealing with, among others, the production, transportation and supply of food, fuels, medicines and paramedical materials to businesses selling these goods, only upon reasoned decision by the company's management.

D. Reduction of VAT Rate Applicable to Personal Hygiene and Protection Products

1. Article 1 of the Act of Legislative Content of 14 March stipulates that the VAT rate for personal hygiene and protection products, such as surgical masks, medical gloves, ethyl alcohol, soaps, antiseptic solutions and antiseptic wipes is 6%.

E. Maximum Quantities of Personal Protection and Hygiene Products

1. Article 68 of the Act of Legislative Content of 20 March provides that customers are allowed to purchase up to three items of disinfectant, ethyl alcohol and antiseptic products.

F. Donations and Requisition of Medicines, Hospital Medical Equipment and Personal Protection and Hygiene Products

1. Articles 6 and 8 of the Act of Legislative Content stipulate that any person or legal entity may donate:
 - a. medicines;
 - b. hospital medical equipment; and
 - c. personal protection and hygiene productsto public and private hospitals, Regional Health Districts (DYPEs) and any institution supervised by the Ministry of Health, as well as to all public health structures to assist in the effort to combat the spread of the COVID-19 coronavirus.
3. These donations must be approved as soon as possible by way of a declaration of the Minister of Health, who will decide to which organisation the products will be donated.
4. Medicines, hospital medical equipment, personal protection and hygiene products may be requisitioned for up to 6

months by joint decision of the Ministers of Development and Investment and Health.

G. Urgent Invitation for Purchase of Medical Devices by Way of Derogation from Public Procurement Provisions

1. Articles 7 and 12 of the Act of Legislative Content of 14 March provide that the National Emergency Assistance Center (EKAB) may issue a call for direct purchases of ambulance spare parts and medical equipment on the basis of the lowest bid and acquire sufficient quantities to meet emergencies, by way of derogation from all existing national public procurement provisions.
2. Similarly, the National Organisation for Public Health (EODY) may directly outsource services to private healthcare providers (diagnostic laboratories) at the lowest price from the services which are immediately available.

H. Electronic Prescription and Delivery of Medicines

1. Articles 36, 49, 50, 51 and 53 of the Act of Legislative Content of 20 March 2020 provide for the facilitation of the issuance of electronic prescriptions so that physical contact of doctors and patient is avoided.
2. Intangible prescriptions and medical referrals are now handled and executed by the First-Degree Healthcare System (<https://www.e-syntagografisi.gr/p-rv/p>), which is operated and managed by IDIKA SA.
3. Patients can log in to the electronic First-Degree Healthcare System or use their taxisnet passwords and will be notified by email or SMS.
4. Physicians may re-issue the prescription upon request of their patients by telephone, fax, email or SMS.
5. Patients, together with their first and second degree relatives or authorized third parties, can obtain the medication from pharmacists by providing them with the prescription barcode.
6. Medicines can also be delivered by a certified courier company to vulnerable groups and patients who are in isolation.

I. Approval of Technical Specifications for Urgent Supplies for Vital Public Health Needs

1. Article 16 of the Act of Legislative Content of 11 March 2020 (Official Government's Gazette A/55) stipulates that technical specifications, required quantities and delivery times for the products and services to be supplied in order to meet public health emergencies of public hospitals and other legal entities supervised by the Regional Health Districts (DYPEs) against COVID-19, are approved by decision of the Central Council of Health Regions (KESYPE).

J. Prohibition of Exports of Paracetamol and Products Necessary for the Treatment of COVID-19

1. By way of its decision 33887/13.03.2020, the National Organisation for Medicines (EOF) extended the prohibition of parallel export and intra-Community movement to include paracetamol products and products necessary for the treatment of COVID-19.
2. The EOF has advised that supply obligations of Greek affiliates towards their Cyprus partners may be exempted if

based on contractual commitments and to the extent regular local supply is not impacted.

K. Electronic Submission of Requests to the EOF

1. On 23 March 2020, the EOF announced that requests must be submitted to its protocol service via the email address protokollo@eof.gr from 24 March 2020 onwards.
2. The application form and any attached documents must be in a pdf format and the size of the message can be up to 20MB.

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