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Recent Developments in Life Sciences & Healthcare: Urgent Measures Relating to the Covid-19 Pandemic

This Briefing provides an overview of the Act of Legislative Content dated 30 March 2020 and the EOF's new Circular dated 23 March 2020 which introduce measures in relation to the Life Sciences and Healthcare Sectors

In This Issue

A. Off-label Administration of Authorised Medicines to Covid-19 Patients

Articles 36-37 of the Act of Legislative Content of 30 March 2020 (Official Government Gazette A/75) stipulate that:

1. The off-label administration of medicines for which a marketing authorisation has been granted and which may be effective against Covid-19, can be provided by a Ministerial Decision of the Minister of Health following the opinion of the National Committee for the Protection of Public Health against Covid-19. This decision defines the approved treatment regimens with reference to active substances, forms, content and dosage.
2. Physicians can administer an approved antiviral treatment in accordance with the above in the following categories of patients:
   a. patients who have developed severe pneumonia due to exposure to the virus; and
   b. patients with mild or moderate symptoms also suffering from other diseases, with risk or age factors or laboratory evidence for an adverse outcome.
3. Physicians shall submit the following documents to the platform of the Electronic Pre-Approval System (SIP) of the National Organization for the Provision of Health Services (EOPYY):
   a. an informed consent signed by the patient or their relatives;

b. the physician's solemn declaration for the need of off-label administration of medicine;
c. the approval of the Director of the hospital clinic, where the medicine shall be administered; and
d. any other document required by the platform.

4. The National Organisation for Medicines (EOF) confirms the off-label use and EOPYY validates the notification by indicating 'complete notification for Covid-19'.
5. Relevant processing of personal data is necessary for public health reasons. Appropriate measures for the protection of fundamental rights and freedoms have been taken. Any processing of personal data for other purposes is forbidden.
6. Physicians shall comply with their obligations relating to pharmacovigilance. The director of the clinic where off-label administration takes place must notify the EOF of safety and efficacy data with the indication 'Off-label Covid-19' every fortnight or earlier, if deemed necessary.

B. Early Access of Covid-19 Patients to Non-Authorised Medicines

Article 38 of the Act of Legislative Content of 30 March 2020 stipulates that:

1. A special procedure for urgent early access of Covid-19 patients to non-authorised medicines (compassionate use) is introduced by way of derogation from the legislation in force (Ministerial Decision ΔΥΓ3α/Γ.Π.85037/10/2011 - Official Government Gazette B/558). The compassionate use of medicines against Covid-19 is permitted under the following conditions:
   a. the requirements for normal inclusion of a patient in a clinical trial are not met;
   b. the pharmaceutical company conducting an Early Access Program for Covid-19 patients should submit to the EOF an application to include patients to the Program;
   c. the EOF authorises the Program;
   d. the pharmaceutical company publishes through its website the necessary information about the Program, the criteria for inclusion and exclusion of patients, as well as a specific request form to be completed by a physician;
   e. early access must be based on the available data and justified on the basis of unsatisfactory results of the available off-label treatments; and
   f. the Scientific Board of the Hospital has been notified about the Program and the Director of each Clinic or Unit has agreed to its implementation.
2. The pharmaceutical company conducting an Early Access Program has the obligation to notify the EOF of hospitals and physicians who have requested the inclusion of patients in the Program.
3. Physicians shall comply with their obligations relating to pharmacovigilance. In addition, the pharmaceutical company must notify the EOF every fortnight or earlier, if deemed necessary, of:
   a. any serious adverse reactions;
   b. the number of enrolled patients per clinic; and
   c. the safety and efficacy data with the indication 'Early-COVID-19'.
4. Access to non-authorised medicines may be also given on an individual basis in cases where no Early Access Program is in place.

C. Reimbursement for Medicines Administered to Covid-19 Patients

Article 39 of the Act of Legislative Content of 30 March 2020 stipulates that:

1. Any off-label administration of medicines to Covid-19 patients will be fully reimbursed without the requirement for an official reimbursement approval prior to the administration.
2. The cost of inclusion of a patient in an Early Access Program for Covid-19 patients will be

covered by the pharmaceutical company conducting the Program.

3. Every prescription relating to off-label administration of medicines to Covid-19 patients must be archived and kept for two years.

D. Establishment of the Covid-19 National Patients' Registry

Article 29 of the Act of Legislative Content of 30 March 2020 stipulates that:

1. A Covid-19 National Patients' Registry is established in which information on the name, age, gender, underlying diseases and health condition of each patient shall be recorded.
2. All public and private healthcare service providers, as well as healthcare professionals in Greece must immediately report every Covid-19 case which they know of to the National Patients' Registry and the National Public Health Organization (EODY).
3. The Ministry of Health is the Data Controller and must ensure that:
   a. the necessary technical and organisational security measures are taken;
   b. access to and processing of personal data is permitted only following use of appropriate credentials by authorised personnel;
   c. data transfers take place through encryption; and
   d. system users do not have access rights to other system data.
4. Special categories of personal data are processed when:
   a. processing is necessary for the purposes of prevention, diagnosis, treatment, management of the healthcare system or on the basis of an agreement with a healthcare professional; and
   b. processing is necessary for reasons of public health, such as the safety of healthcare and medicines and protection of the population against spread of the virus; appropriate measures must be taken to safeguard the rights and freedoms of the data subject, in particular professional secrecy.
5. The E-Government Center for Social Security (IDIKA) is designated as Data Processor.
6. Authorised personnel is bound by confidentiality in accordance with the Code of Medical Ethics, the Public Servants' Code of Conduct and the Criminal Code.
7. Patients shall have the right of access to their information and all other rights set out in the General Data Protection Regulation (GDPR) and any other applicable law.
8. The attending physician and doctors providing healthcare services are the recipients of the data.
9. The Ministry of Health, supervised bodies or other public services may receive pseudonymised or anonymised data, where transmission to them is necessary for reasons of substantial public interest.
10. Covid-19 European Patients' Registries may receive pseudonymised or anonymised information, from which no direct or indirect identification of data subjects may occur, in order to carry out statistical or scientific studies. The Ministry of Health may also publish aggregate information in statistics.
11. It is strictly prohibited to provide special categories of personal data to insurance companies and banks even if a data subject has consented to it.
12. Anyone who unlawfully interferes with the Covid-19 National Patients' Registry may be punished by imprisonment and a fine and, in the case of sensitive data (such as health data), by imprisonment of at least one year and a fine of at least €20,000. Imprisonment of up to 10 years and a fine of at least €50,000 shall be imposed if unlawful benefit or harm to a third party was intended.

E. Establishment of Volunteers' Program Registry

Article 35 of the Act of Legislative Content of 30 March 2020 stipulates that:

1. A Volunteers Program is established by way of which adults not belonging to vulnerable groups may voluntarily provide their services to hospitals and health structures.
2. As part of the program, an electronic filing system is established which will contain personal data, including identification information and the necessary health data of participants.
3. The Ministry of Health is the Data Controller and competent authorities shall be the recipients of the data only for reasons of substantial public interest.
4. Participants have rights of access, rectification, erasure and restriction of processing of their data, as well as the right to object.

F. Conversion of Hospital Facilities to Intensive Care Units

Article 30 of the Act of Legislative Content of 30 March 2020 (Official Government Gazette A/75) stipulates that:

1. Any public or private hospital facility or other conceded property can be converted to high dependency unit or intensive care unit by decision of head of the hospital or clinic concerned, provided that such needs cannot be met differently.

G. Purchase of Materials and Reagents for Diagnosis of Covid-19 Patients by Way of Derogation from Public Procurement Provisions

Article 34 of the Act of Legislative Content of 30 March 2020 stipulates that:

1. The National Blood Donation Centre (*EKEA*) is responsible for laboratory tests for the diagnosis of Covid-19 patients.
2. By way of derogation from applicable legislation, EKEA may conclude direct agreements for the supply of materials and reagents in order to conduct Covid-19 tests. A relevant invitation is posted on EKEA's website for a period of three days and the award of the agreement is based solely on the lowest bid and the purchase of sufficient quantities to meet emergencies.

H. Organisation of Scientific Events during Summer 2020 by Exception

1. Pursuant to the new Circular of the National Organisation for Medicines (EOF) dated 23 March 2020, scientific events may be organised during the summer of 2020 by way of derogation from the general prohibition of scientific events to take place in the summer period. This exception has been provided as all events in Greece have been suspended due to the Covid-19 pandemic.
2. On the contrary, scientific events shall not take place in tourist destinations during the winter season from 15 December – 15 January and in exclusively ski destinations from 15 December - 15 March.
3. Pharmaceutical companies that wish to sponsor the participation of a Healthcare Professional in such events must follow the ordinary online submission procedure in order to obtain approval from the EOF.

I. Scientific Events Sponsorship Limits

1. The EOF's Circular dated 23 March 2020 provides for the following sponsorship limits for scientific events:
   a. National Panhellenic congresses are held once a year by scientific institutions relevant to medical specialties recognised by the Central Health Council (KESY) and/or scientific institutions operating for a minimum of 4 years and demonstrating scientific and educational work. The duration of these events must be at least two days, they must have a minimum of 100 participants and sponsorship can amount up to €30,000 per company;
   b. sponsorship of scientific events with a duration of more than 8 hours cannot exceed €15,000 per company;
   c. sponsorship of scientific meetings organised by scientific institutions lasting one or two days respectively, regardless of the number

of participants, is limited to €5,000 per company; and

d. scientific events organised by Public Health Institutions may not exceed two days and sponsorship can be up to €2,500 per company with a maximum of €10,000 from all sponsoring companies.

J. Scientific Events Reporting Data

1. Within the year in which each scientific event takes place and until 1st June of the following year, the following data must be reported to EOF's electronic platform:

a. the event's financial report (revenue and expenditure) as well as a list of sponsors, sponsorship amounts and the number of participants, submitted by the organiser; and

b. a list of sponsored healthcare professionals and analysis of their actual costs submitted by the companies/sponsors.

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