

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

This Briefing provides an overview of Law 4683/2020 ratifying the Act of Legislative Content dated 20.03.2020 on Emergency Measures due to the spread of Covid-19 and other provisions (Official Government Gazette A/83)

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A. Generic Medicines Are Included in the Reimbursement List in Accordance with the Opinion of the Negotiation Committee

1. Original medicines are included in the positive reimbursement list only upon positive evaluation by the Evaluation and Reimbursement Committee and reasoned opinion of the Negotiation Committee of the Ministry of Health.
2. Up to now, the reimbursement of generic medicines was not subject to the above procedure if:
 - a. the medicines contained the same active

substance and were prescribed for the same indications as other already reimbursed medicines; and

- b. their ex-factory price was equal to or less than 65% of the ex-factory price of the reference product.

3. Articles 13 and 14 of Law 4683/2020 (the New Law) stipulate that the Negotiation Committee of the Ministry of Health is now competent to issue a reasoned opinion regarding the inclusion of all generic products in the positive reimbursement list, even if they fall within the category mentioned above.

B. Establishment of a Special Evaluation Sub-Committee for the Administration of Medicines Not Included in the Reimbursement List

1. A Special Evaluation Sub-Committee is established by virtue of Article 15. It is competent to issue opinions on the exceptional administration of medicines which cumulatively:
 - a. are not included in the positive reimbursement list;
 - b. have not been evaluated; and
 - c. need to be administered to patients with life-threatening diseases or diseases which may

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cause irremediable damage to human health.

2. The Minister of Health shall approve the Rules of Procedure of this Sub-Committee.
3. Until the Sub-Committee is set up as above, applications for the exceptional administration of medicines shall be reviewed by the Evaluation and Reimbursement Committee referred to in Article 247 of Law 4512/2018.

C. Former Regulatory Framework for Clinical Studies Comes Back into Force

1. Article 17 of the New Law stipulates that Article 4 of Law 4523/2018 (Official Government Gazette A/41) is repealed.
2. In accordance with the Explanatory Memorandum of the New Law, the previous regulatory framework governing clinical studies in Greece comes back into force, since the repealed provision has not been applied in practice.
3. The Greek National Organisation for Medicines (EOF) remains competent for post-authorisation safety studies, while submitted files of other clinical studies have to be referred to the relevant authorities.

D. Extension of Agreements with EOPYY Providers

1. Pursuant to Article 22 of the New Law, the following categories of agreements concluded by the National Organisation for the Provision of Healthcare Services (EOPYY) and its service

providers which are due to expire during the next trimester, are automatically extended for three months but not later than 10 October 2020. These categories are:

- a. supply of healthcare equipment and medical devices;
- b. supply of hearing aid devices, orthopedic and respiratory devices/equipment;
- c. supply of diet foods intended for special medical use;
- d. supply of optics; and
- e. supported accommodation shelters.

E. Legalisation of Expenditures of Public Hospitals, YPEs and EOPYY

1. Article 6 provides for the legalisation of expenses of National Health Service (ESY) Hospitals and Regional Health Districts (YPEs) for supplies of materials, goods and services, which:
 - a. were provided up to 31 March 2020;
 - b. were provided without a written agreement;
 - c. are not mentioned in the Price Observatory of the Committee of Healthcare Supplies (EPY); and
 - d. fall within the approved budgets.
2. Article 21 stipulates that EOPYY expenses which were incurred during 2019 and relate to services provided by the Electronic Government of Social Security SA (IDIKA SA) amounting to €1,163,336.02 are legal and payable to the beneficiary.

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