***Dear Members,***

This is to inform you that **Government Gazette Series Α, Issue No. 16/31.1.2020** was issued today, comprising ***Law 4655/2020 “Ratifying the individual donation agreements which form part of Donation Agreement dated 6.9.2018 between “Stavros S. Niarchos Foundation” and the Greek State, to enhance and upgrade infrastructures in the health sector, as same was ratified by Law 4564/2018 and other provisions”.***

The Law comprises of 6 Articles, yet Articles 2, 4 and 5 of which are mostly important for us.

Below is a summary of the Law’s contents:

**Article 2: Regulations on former EKAS beneficiaries**

This provision extends the term of the compensatory measure of exemption from participation in pharmaceutical expenditures for former EKAS beneficiaries, who have permanently forfeited EKAS pursuant to Article 92 of Law 4387/2016 for the period 1.1.2020 - 31.12.2020. For this reason, and in order to materialise the exemption of former EKAS beneficiaries from participating in pharmaceutical expenditures as of 1.1.2020, this regulation shall be afforded **retroactive effect**  as of the date of effect indicated in this Article.

**Article 4: High-Cost Medicines (HCMs) Delivery Procedure**

The introduced regulation is an amendment to Article 22(9)of Law 4213/2013 [sections (f), (g) and (h)]. The new regulation is intended to optimise the healthcare services and to facilitate healthcare beneficiaries by simplifying the delivery procedures of any High-Cost Medicines (HCMs) (as same are defined in Article 12 of Law 3816/2010), which hold no marketing authorisation exclusively for hospital use. These regulations define the procedure for selection of the **delivery point** by the patients, as well as the procedure for delivery of medicines to third parties acting on account or on behalf of the patients.

In summary the regulation provides the following: “EOPYY may deliver to private pharmacies, to distribution points of Healthcare Regions (EOPYY distribution channel) or directly to the insured, High-Cost Medicines, as same are defined in Article 12 of Law 3816/2010, which hold no marketing authorisation exclusively for hospital use, as these medicines are defined by decision of the Minister of Health following a recommendation EOPYY’s Board of Directors. As regards in particular the selection of final delivery points by private pharmacies, the patient pre-designates a private pharmacy through the HCM delivery application by prescription. The pharmacists collaborating with EOPYY under any employment agreement shall carry out a preliminary control of the execution of each prescription through use of an electronic signature. [for more information on such preliminary controls, please refer to Article 4 ] […] Through the same application, patients are notified if their requests for delivery of their HCMs at the pharmacies of their choice are authorised. The orders are executed by EOPYY’s drug storage departments [...]. These departments may operate in accordance with the provisions of Article 13(12) of Law 4052/12. **Delivery of the medicine is certified by the private pharmacist exclusively by signing the dispatch note.** The signed dispatch note **is then submitted by the pharmaceutical company to EOPYY, together with the relevant invoice and accompanies the relevant payment order.** Delivery is completed when the pharmacist has thoroughly completed all actions prescribed in Law 3892/2010 on the Social Security e-Governance platform (HDIA SA).[…] Any other details necessary to carry out this process shall be regulated by decision of the Minister of Health, following a recommendation by EOPYY’s Board of Directors.

**Article 5: Development of an “Application for Distribution of High-Cost Medicines (HCMs)” to Private Pharmacies - Processing Purpose**

This regulation specifies certain matters pertaining to the operation of the platform entitled “Application for Distribution of High-Cost Medicines (HCMs)”. It specifies the purpose of the operation of the platform; regulates the processing by EOPYY of the data which are entered by EOPYY in the application on account of the Ministry of Health, and lays down the necessary safeguards which ensure the system’s integrity and the security of personal data.

In summary, the regulation provides the following:  The Ministry of Health, as data controller, shall create a digital application with the name “Application for Distribution of High-Cost Medicines (HCMs)”, which will be accessible to patients online and will enable HCM beneficiaries to indicate the place of delivery of their HCMs, i.e. a private pharmacy or their place of residence. **The application may not contain the personal health record of the healthcare beneficiary.** EOPYY’s pharmacists shall log in the HDIKA system exclusively for the purpose of carrying out the necessary preliminary controls before dispatching the medicines to the designated place of delivery. The only personal data which will be collected and undergo further processing in the context of the application will be the pharmacy designated as delivery point by the insured and/or the designated residential address/delivery point, after the option is activated. These data will be collected and undergo processing for the exclusive purpose of executing the delivery of the medicines to the designated private pharmacies or residential addresses. **The application will be activated by the insured through use of his/her *taxisnet* credentials and Social Security Number (“AMKA”)**. If the beneficiary is a minor person, the same applies to his/her parent or to the person exercising parental care. **EOPYY is designated as Processor** in the application to be operated on account of the Ministry of Health . In this context, EOPYY shall bear all obligations applicable to data processors under the General Data Protection Regulation in conjunction with the provisions of Law 4624/2019. Any technicalities necessary to put the application in effective operation shall be regulated by decision of the Minister of Health and the Minister of e-Governance.

**The processing of any special categories of data involving health data, which may be entered in the “Application for Distribution of High-Cost Medicines (HCM)” for the purpose and under the procedure defined hereunder may not entail the processing of personal data for any other purposes by third parties, such as, by way of indication, by pharmaceutical or insurance companies. This restriction shall not be lifted even the data subject has granted his/her consent.\*\*\***

**The new provisions – save for those referring to EKAS beneficiaries, which have retroactive effect - shall enter into effect as of 31.1.2020.**

**\*\*\*\***

For reasons of completeness of this memo, we also make brief reference to the ratification of the individual donation agreements that were entered between the Stavros Niarchos Foundation and the Greek State (GS), as stated in Article 1 of the Law.

These are four (4) donation agreements, i.e. two main and two secondary.

The first one, which was entered by the GS, the SN Foundation and the National and Kapodistrian University of Athens, relates to the procurement of special medical equipment and to training and research programmes, and has a total value of EUR 2,913,288.00 (VAT included).

The second agreement, which was entered by the GS, the SN Foundation and Evangelismos Hospital / Athens Eye Clinic, relates to the procurement of special medical/technical equipment and the implementation of post-graduate programmes and scholarships, and has a total value of EUR 2,897,000 (VAT included).

Both agreements will be implemented through a special-purpose vehicle named “Health Initiative”.

The third individual agreement, which was entered by the GS, the SN Foundation, Health Units SA and the National and Kapodistrian University of Athens, relates to the procurement of medical/technical equipment and training of physicians / surgeons on surgical simulation at the “AKISA” University Complex, in “Atticon” General University Hospital, forms part of a sub-project on **Injuries** and has a total value of EUR 6,100,000 (VAT included), and

The fourth agreement, which was entered between the GS and the SN Foundation, relates to **Infections**, and has a total value of EUR 5,000,000 (VAT included).

*As regards infections in particular, it is worth noting that it is acknowledged in the agreement that hospital infections are infections which attack patients during their hospitalisation and constitute a major problem for public health worldwide. Based on the findings of a research that was recently published in Greece, this generates extremely serious implications for the healthcare system, as patients remain hospitalised for longer periods of time, which in turn increases impressively hospitalisation expenses and mortality rates. Moreover, several hospital infections (His) are caused by germs which are resistant to many or all known antibiotics, making microbial resistance (MR) one of the major public health problems which, according to the WHO, requires a "global action plan” .*

*For these reasons, the donation serves the development of a five-year HI and microbial resistance (MR) prevention and control programme, which is mainly intended to render the Greek public hospitals ideal in terms of HI and MR prevention and control, through the following steps:*

1. *Supporting the infections committees of selected hospitals by providing nursing staff, so that the total-number-of-nurses to total-number-of-beds ratio is 1 nurse for 250 beds.*
2. *Implementing a HI monitoring system, HI prevention practices and promoting the use of antibiotics.*
3. *Designing and implementing interventions intended to improve HI and MR prevention and control practices.*
4. *Designing a training programme which serves the above purposes and the needs to expand the control system throughout the country.*
5. *Creating a national training programme which integrates the basic HI and MR prevention and controls principles.*

*Given that it has been solidly established that this type of programmes cannot be successful unless health professionals are willing to change their attitude, it is imperative that the Ministry of Health and the State in general are actively committed to implementing this Programme.*

Any persons who may be specifically affected by the new Law’s regulations are kindly advised to familiarise themselves with the provisions of the new Law.

The relevant file is too large to attach, but you can download it at www.et.gr by clinking on the “Search for GG \_A\_2020” field.

On behalf of SFEE,

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