



HELLENIC REPUBLIC
MINISTRY OF HEALTH
NATIONAL ORGANIZATION FOR MEDICINES
Mesogeion 284,15562 Cholargos
Directorate: Control of production and circulation of products
Department: Circulation Control
Information: N. Boufidis
Telephone number: 2132040540
Email: market-surveillance@eof.gr

EXPIRATION OF THE LICENCE: 21/4/2027

Cholargos, 21/4/2022

Protocol number: 4221

To: ALFAOMEGA S.A.

Location Lakko Kyrillo

19300 Aspropyrgos

P.O BOX 152

**SUBJECT: Renewal of the License for the Wholesale of Medicinal Products
for Human Use of the Alfaomega S.A.'s pharmaceutical warehouse.**

DECISION

Taking into consideration:

1. The provisions of the Law 1316/1983 (Government Gazette(ΦΕΚ) 3 Α'/11-1-1983), as in force and in particular the case g)(ζ) of par. 1 of article 3 which was set with par. 1 of art. 17 of Law 4052/2012 (Government Gazette(ΦΕΚ) 41 Α'/1-3-2012).

2. The provisions of the Legislative Decree(ΝΔ) 96/1973 (Government Gazette(ΦΕΚ) Α 172) and in particular the article 19, as in force.

3. The provisions of Joint Ministerial Decision(Κ.Υ.Α.) under no. ΔΥΓ3α/Γ.Π.32221/2013 (Government Gazette(ΦΕΚ) 1049 Β'/29-4-2013) about the "Harmonization of the Greek legislation with the respective EU legislation. in the field of production and distribution of medicinal products for human use, in accordance with sub-no.2001/83/EC Directive "on the Community code relating to medicinal products for human use" (L 311/28.11.2001), as it stands and as amended by Directive 2011/62/EU, regarding the prevention of the entry of counterfeit drugs into the legal supply chain (L174/1.7.2011)", as amended by the Joint Ministerial Decision(Κ.Υ.Α.) ΔΥΓ3α/Γ.Π.οικ. 90023/2013 (Government Gazette(ΦΕΚ) 2485 Β'/3-10-2013).

4. The no. 96870/8-11-14 Interpretative Circular on the National Organization for Medicines'(ΕΟΦ)Wholesale Sales Licenses.

5. The no. 4221/17.1.2022 application of the ALFAOMEGA S.A's pharmaceutical warehouse.

6. The 7-8/4/2022 National Organization for Medicines'(ΕΟΦ) inspection based on the Guidelines 2013C/343/01.

WE DECIDE

To renew the Wholesale Sale License of Medicinal Products for Human Use of the **ALFAOMEGA S.A.**'s pharmaceutical warehouse which is based in the Municipality of Aspropyrgos, located in Lakko Kyrillo where the pharmacist in charge is Mrs. Angelopoulou Asimina.

This license is in effect for five years and the company is required to comply with the Guidelines of the 5th of November 2013 on good distribution practice of medicinal products for human use (2013/C 343/01).

Head of National Organization for Medicines

Demetris Filippou

C/C (sharing)

- HELLENIC MINISTRY OF HEALTH, Directorate of Medicines and Health Products.

Aristotelous 17, 101 87 Athens.

- Panhellenic Association of Pharmaceutical Wholesalers.

Veranzerou 34, Athens 10432.

Internal Distribution:

- Directorate of Control of production and circulation of products – Department of Circulation Control (2).

(Official seal)

(HELLENIC REPUBLIC-MINISTRY OF HEALTH-NATIONAL ORGANIZATION FOR MEDICINES)

TO ENSURE ACCURACY AND LIABILITY

THE HEAD DEPUTY OF THE GENERAL SECRETERIAT

(Signature of Demetris Petropoulos)

BAΣΙΛΕΙΟΣ Ζ. ΜΕΛΕΓΟΣ
ΔΙΚΗΓΟΡΟΣ
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Ακριβές αντίγραφο από την Ελληνική στην Αγγλική γλώσσα του συνημμένου εγγράφου σύμφωνα με το αρ. 36§2 Ν. 419 του Κώδικα περί Δικηγόρων. Η ως άνω μετάφραση έχει πλήρη ισχύ έναντι οποιασδήποτε αρχής σύμφωνα με το ανωτέρω.

Βεβαιώνω ότι έχω επαρκή γνώση της γλώσσας από και προς την οποία μεταφράζω.

Αθήνα 27/05/2022

Ο δικηγόρος που μεταφράζει και βεβαιώνει

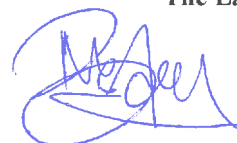


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This is to certify that the document is a true translation which was translated and authenticated in accordance with the Code of Lawyers, made by the undersigned, who is conversant in both the Greek and the English language.

Athens, 27/05/2022

The Lawyer



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