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DATE

CORRECT REPETITION OF 18.08.2020 EXPIRATION 06/08/2025

Cholargos, 6.8.2020 Ref no: 81114

To: MARIO D. KATSIKAS S.A.

6 Louvari& Paparigopoulou street

P.C. 12132 Peristeri Greece

HELLENIC REPUBLIC MINISTRY OF HEALTH

NATIONAL ORGANIZATION FOR MEDICINES

284 Mesogeion P.C. 15562 Cholargos Directorate for Product control and Market of products Department of Market Surveillance

Enquiries: N. Boufidis Tel: +302132040540 Fax: +302106549500

e-mail market-surveillance@eof.gr

Subject: Renewal of the wholesale distribution authorization to the Wholesale Pharmacy MARIO D. KATSIKAS S.A.

DECISION

Having regard to:

- 1. The Provisions of Law 1316/1983 (Gov. Gazette 3 A/11-1-1983), as applicable and in particular indent f of par.1 of article 3 which was entered by par.1 of art. 17 of Law 4052/2012 (Gov. Gazette 41 A/1-3-2012).
- 2. The provisions of the Legislative Decree 96/1973 (Gov. Gazette A 172) and in particular of article 19 as applicable.
- The provisions of the Joint Ministerial Decree no DYΓ3α/ G.P.32221/2013 (Gov. Gazette 1049 B/29-4-2013) on "Harmonization of the Greek Legislation with the respective EU legislation in the field of production and market of medicinal products for human use, in compliance with the Directive no 2001/83/EC "on the community code for medicinal products for human use (Law 311/28.11.2011), as applicable and as amended by Directive 2011/62/EU as regards the prevention of the entry into the legal supply chain of falsified medicinal products (Law 174/1.7.2011) as amended by the Joint Ministerial Decree DYΓ3α/ G.P our ref 90023/2013 (Gov. Gazette 2485 B/3-10-2013).
- The interpretative circular no 96870-8.11.2014 on wholesale distribution authorizations of the National Organization for Medicines.
- 5. The request for renewal no 58506/3.6.2020 and the document no 61854/11.6.2020 with additional information of the wholesale pharmacy MARIO D. KATSIKAS S.A.
- 6. The provisional wholesale distribution authorization no 58506/22.6.2020 of the wholesale pharmacy MARIO D. KATSIKAS S.A. from the National Organization for Medicines.
- The inspection dated 15/7/2020 by the National Organization for Medicines in accordance with the guidelines 2013/C 343/01.

WE DECIDE

To renew the wholesale distribution authorization for medicinal products to the wholesale pharmacy MARIO D. KATSIKAS S.A. based in the Municipality of Peristeri at the address 6 Louvari & Paparigopoulou street with pharmacist in charge Mr. Katsikas Marios

This is a five-year authorization and the company must comply with the guidelines of November 5th 2013 on Good Distribution Practice of medicinal products for human use (2013/C343/01)

This authorization abolishes the provisional wholesale distribution authorization renewal under no 58506/22.6.2020 for the medicinal products of the wholesale pharmacy.

The President of NOM acting as Vice President of NOM **Eleftherios Pallis**

	13 JAN 2021
DATE	

Notification

- MINISTRY OF HEALTH Directorate for Medicinal Products & Health Products
 17 Aristotelous str. 10187 Athens
- Panhellenic Organization of Pharmaceutical wholesalers 34 Veranzerou street Athens GR 19432 <u>Internal Distribution</u> Department of Market Surveillance (2)

Certified for its accuracy
THE DEPUTY HEAD OF THE GENERAL SECRETARIAT
CHARALAMPIA MAROUDA
Signed/Sealed

Official, accurate and faithful translation is executed and notarized in accordance with the law of the Hellenic Republic, in translation office "Athens Translation Center". Head of the department Mr. E. Kourtsidis

Exact and true translation of the attached_text.

Athens ... 1.3. JAN 2021 .. 200

EVGENIOS KOURTSIDIS

of notary and translation sections of

