



HELLENIC REPUBLIC
MINISTRY OF HEALTH



εθνικό
οργανισμό
φαρμάκων
national
organisation
for medicines

NATIONAL ORGANISATION FOR MEDICINES

www.eof.gr

284 Mesogion Av., 15562 Cholargos

PRODUCT ASSESSMENT DIVISION

VETERINARY MEDICINES ASSESSMENT SECTION

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Cholargos : 03/06/2025

Protocol Nr : 65129/30-05-2025

To: List of Receptients

Subject: Applications for renewal of marketing authorization of veterinary products expiring 31-12-2025

This is to inform the interested parties that the applications for the indefinite renewal of the veterinary medicinal products licences authorized by national, mutual or decentralized procedure with expiration date **31-12-2025**, will be accepted by the Veterinary Medicines Assessment Section of the National Organization for Medicines electronically, via CESP until **31-07-2025 starting from today**.

Your submission shall include the following:

1. Application of renewal (**via CESP**), one separate application for each marketing authorization
2. Summary product characteristics (SPC)
3. Inner and outer packaging (Labelling) and user information leaflet (PIL)
4. Copy of the actual MA licence, along with the stamped SPC, labelling and PIL, and any variation issued since
5. Fee of 1500€ per trade name provided that **they are submitted simultaneously** (should be included in one CESP submission)

PLEASE NOTE

The interested parties are requested to note the following:

- a. The renewal application can not include any type of variation of the MA license, unless an variation application has already been submitted
- b. If products are not intended to be renewed, please submit a **withdrawal application**
- c. Upon fail to submit the renewal application within the required timeframe, the existing provisions regarding the ban of the circulation of the specific products shall be applied.
- d. The fee must be deposited to the Bank of Greece (IBAN: GR5301000240 000000000263038, SWIFT CODE: BNGRGRAA, Account number: 263038). The proof of payment (POP) which should be included in the CESP documentation, must indicate as justification: "RENEWAL / tradename"
- e. The signed cover letter of the renewal application must be sent to protokollo@eof.gr

In case **this notification concerns you** but you are not included in the list of recipients, please contact the Veterinary Medicines assessment section at vet@eof.gr

The Veterinary Medicines assessment section shall remain at the disposal of interested parties for relevant clarifications and explanations.

The President of EOF

E. Manolopoulos

LIST OF RECIPIENTS: attached

INTERNAL DISTRIBUTION

1. *President's office*
2. *Veterinary Medicines Assessment Section*
3. *Validation and Registration of Applications Section*
4. *Information and Public Relations Division*

LIST OF RECIPIENTS

ALPHA-VET	Hoffher Albert Utca 42, Kerulet, Budapest, H-1194, HUNGARY
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BELA-PHARM GMBH & CO. KG ALTAVET EE MONSIEUR ANIMAL	Lohner Strasse 19, Vechta Lower Saxony, 49377, Germany Λεωφόρος Βενιζέλου Ελευθέρου 48, 16344, Ηλιούπολη MONSIEUR ANIMAL Μ.Ι.Κ.Ε,ΕΛΛΑΔΑ Τροίας 43, 11257, ΑΘΗΝΑ
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DECHRA REGULATORY BV.	Handelsweg 25, Bladel, T.K. 5531 AE, NETHERLANDS
ECUPHAR NV ΧΕΛΛΑΦΑΡΜ (Hellafarm)	Legeweg 157 Bus I, Oostkamp, West-Vlaanderen, 8020, Belgium Λεωφ. Μαρκόπουλου 1ο χιλ, Παιανία 190 02
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