



HELLENIC REPUBLIC
MINISTRY OF HEALTH
NATIONAL ORGANISATION FOR MEDICINES
Division: Product Assessment Section
Section: Veterinary Medicines Assessment
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Cholargos, 11-11-2022
Protocol Nr.: 120144
To: Attached List

Subject: Applications for renewal of marketing authorization of veterinary products expiring 31-12-2022

This is to inform the interested parties that the applications for the indefinite renewal of the veterinary medicinal products licences authorized by national or mutual or decentralized procedure with expiration date **31-12-2022**, will be accepted by the Veterinary Medicines Assessment Section of National Organization for Medicines electronically, via CESP until **28-01-2023 starting from today.**

Your submission shall include the following:

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

ATTENTION

The interested parties are requested to note the following:

- a. The renewal application must not include any type of variation application of the MA licence.
- b. For the products that you do not wish to renew, please submit a **withdrawal application** via CESP
- c. Fail to submit the renewal application within the required timeframe, the existing provisions regarding the ban of the circulation of the specific products will be applied.
- d. The amount of 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 also be sent to protokollo@eof.gr

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

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

The President of EOF

Dimitris Filippou

LIST OF RECIPIENTS: attached

INTERNAL DISTRIBUTION

1. Product Assessment Division
Veterinary Medicines Assessment Section
2. Validation of Applications and Issue of Marketing Authorizations Division
Validation and Registration of Applications Section
3. Information and Public Relations Division

LISTS OF RECIPIENTS:

- 1) **ΧΕΛΛΑΦΑΡΜ Α.Ε.**
1° χλμ. Λ. Παιανίας Μαρκόπουλου, ΤΚ 19002, Παιανία, Αττική
- 2) **PHARMAQUA ΟΕ Δ. ΚΟΚΚΟΡΗΣ & ΣΙΑ**
Δ. Σολωμού 28, Μεταμόρφωση, ΤΚ 14451, Αττικής
- 3) **ΤΑΦΑΡΜ ΙΩΑΝΝΗΣ ΚΩΝ. ΤΑΤΣΙΡΑΜΟΣ ΕΠΕ**
Χριστιανουπόλεως 108, ΤΚ 11146, Γαλάτσι
- 4) **NEOCELL ΦΑΡΜ/ΚΑ-ΚΤΗΝΙΑΤΡΙΚΑ ΠΡΟΪΟΝΤΑ ΕΠΕ Δ.Τ. NEOCELL ΕΠΕ**
10ο χλμ. Εθνικής Οδού Αθηνών-Λαμίας, ΤΚ 14451, Μεταμόρφωση Αττικής
- 5) **ALTAVET Ε.Ε.**
Ελ. Βενιζέλου 48, ΤΚ 16344, Ηλιούπολη
- 6) **VIRBAC HELLAS Α.Ε.**
13ο χλμ. Αθηνών-Λαμίας, ΤΚ 14452, Μεταμόρφωση Αττικής
- 7) **PETLINE Α.Ε**
Φίνος Φίλμ, Θέση Α. Θωμάς – Χούσιμζα, ΤΚ 19004 Σπάτα Αττικής
- 8) **LEVET BEHEER B.V**
Wilgenweg 7, 3421 TV Oudewater, Holland
- 9) **ΕΛΑΝΚΟ ΕΛΛΑΣ ΑΕΒΕ**
Λεωφόρος Μεσογείων 335, ΤΚ 15231, Χαλάνδρι
- 10) **CYCON HELLAS ΜΟΝΟΠΡΟΣΩΠΗ ΙΚΕ, ΕΛΛΑΔΑ**
Ακαδήμου 101, ΤΚ 56224, Εύοσμος Θεσ/νίκη
- 11) **VETOQUINOL S.A**
34 Rue du Chêne Sainte-Anne, Magny-Vernois, 70200 Lure, Γαλλία
- 12) **LE VET B.V.**
Wilgenweg 7, 3421 TV Oudesater, Holland
- 13) **LABORATORIOS CALIER S.A.**
Carrer Barcelonès 26 - Pla del Ramassa, 08520, Les Franqueses del Valles, Spain
- 14) **CEVA HELLAS ΕΠΕ**
Εθνάρχου Μακαρίου 34, ΤΚ 16341, Ηλιούπολη
- 15) **ZOETIS HELLAS SA**
Φραγκοκκλησιάς 7, ΤΚ 15125, Μαρούσι Αττικής
- 16) **BEAPHAR B.V.**
P.O.Box 7, 8100 AA Raalte, Holland
- 17) **AQUAVET S.A**
Αντιοχείας 48, ΤΚ 14341, Ν. Φιλαδέλφεια