



HELLENIC REPUBLIC
MINISTRY OF HEALTH
NATIONAL ORGANISATION FOR MEDICINES
Product Assessment Division
Veterinary Medicines Assessment Section
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Cholargos, 05-06-2024
Protocol Nr.: 66992
To: List of Recipients

**Subject: Applications for renewal of marketing authorization of veterinary products
expiring 31-12-2024**

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 **31-12-2024**, will be accepted by the Veterinary Medicines Assessment Section of the National Organization for Medicines electronically, via CESP until **31-07-2024 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 actual MA licence, along with the stamped SPC, labelling and PIL, and any variation issued since
5. Fee of 1500€ + 2.4% (1536€) per trade name provided that **they are submitted simultaneously** (relevant eAFs 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 application of the MA license.
- b. If products are not intended to be renewed, please submit a **withdrawal application** via CESP
- 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 will 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 sections 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

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