

(Pielikums MK 03.01.2013. noteikumu Nr.7 redakcijā, kas grozīta ar MK 30.07.2013. noteikumiem Nr.410; MK 31.05.2016. noteikumiem Nr. 338)

Iesniegums veterināro zāļu registrācijai (Eiropas Komisijas veidlapa)

Kopsavilkums
Summary of the dossier

Administratīvie dati
Application Form: Administrative data

Iesnieguma veidlapu izmanto, iesniedzot Pārtikas un veterinārajā dienestā iesniegumu veterināro zāļu registrācijai nacionālajā, savstarpējās atzīšanas vai decentralizētajā procedūrā. Jāiesniedz atsevišķs iesniegums par katru zāļu stiprumu un zāļu formu.

(The application form is to be used for an application for a marketing authorisation of a medicinal product for veterinary use submitted to a Food and Veterinary service under either a national, mutual recognition procedure or decentralised procedure.

Usually a separate application form for each strength and pharmaceutical form is required.)

Deklarācija un paraksts

DECLARATION and SIGNATURE

Veterināro zāļu (piešķirtais) nosaukums/Product (invented) name:

Stipruma(-i)/Strength(-s):

Zāļu forma/Pharmaceutical form:

Aktīvā(-ās) viela(-as)/Active Substance(-s):

Iesniedzējs/Applicant:

Persona, kas pilnvarota pārstāvēt iesniedzēju*/

*Person authorised for communication, on behalf of the Applicant**

Apstiprinu, ka iesniegtā informācija ir pietiekama, lai pierādītu registrējamo veterināro zāļu kvalitāti, drošumu un iedarbīgumu/*It is hereby confirmed that all existing data that are relevant to the quality, safety and efficacy of the veterinary medicinal product have been supplied in the dossier, as appropriate.*

Apstiprinu, ka veterināro zāļu registrācijas izmaksas segtas saskaņā ar Pārtikas un veterinārā dienesta maksas pakalpojumu cenrādi**/*It is hereby confirmed that fees have been paid according to the national rules**.*

Pārstāvēt iesniedzēju/*On behalf of the applicant:*

_____ (paraksts/signature)***

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* Iesnieguma 5.4.apakšpunktā noteiktajā pielikumā pievienot iesniedzēja pilnvarojuma vēstuli/*Please attach letter of authorisation for communication/signing on behalf of the applicant in annex 5.4.*

** Iesnieguma 5.1.apakšpunktā noteiktajā pielikumā pievienot maksājumu apliecinājošu dokumentu/*If fees have been paid, attach proof of payment in Annex 5.1.*

*** Dokumenta rekvizītu "paraksts" neaizpilda, ja elektroniskais dokuments ir sagatavots atbilstoši normatīvajiem aktiem par elektronisko dokumentu noformēšanu.

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