



## ÚSTAV ŠTÁTNEJ KONTROLY VETERINÁRNYCH BIOPREPARÁTOV A LIEČIV

Institute for State Control of Veterinary Biologicals and Medicaments

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### THE ANNUAL MAINTENANCE FEE - VETERINARY MEDICINAL PRODUCTS

Technical and administrative activities related to the Institute for State Control of Veterinary Biologicals and Medicaments

In connection with the supervision and surveillance of authorised veterinary medicinal products that the Institute for State Control of Veterinary Biologicals and Medicaments (hereinafter referred to as the Institute) continuously carries out according to § 95 par. 3 - 5, § 108, § 109, § 125 par. 1 and § 134 par. 2, letter i) and m) of the Act no. 362/2011 Coll. on Medicinal products and medical devices as amended, Marketing Authorisation Holder (hereinafter referred to as MAH) of a veterinary medicinal product pays costs of activities of the Institute associated with the duration of veterinary medicinal products authorisation in the form of annual maintenance fees (hereinafter referred to as the fee).

The fee in sum 300 € generally covers the cost of the register maintaining, information on medicinal products published by the Institute, adverse effect monitoring, processing errors in the quality of medicinal products, development of guidelines, forms and applications, processing of changes other than specified in administrative fees, ATC classification, statistics of medicinal products consumption and other activities related to the continuous surveillance of every authorised product.

The fee is due by 16 April every year.

The fee for a veterinary medicinal product must be credited to the Institute's account latest 30 days from delivering the payment demand; otherwise the fee is increased by 20 %.

The fee is not paid for the calendar year in which the authorisation is given. If the fee is paid for the calendar year in which the veterinary medicinal product authorisation is cancelled or in case of authorisation expiry, the aliquot amount of the fee will be returned at the request of MAH. However, application for reimbursement of the aliquot amount of the annual maintenance fee has to be submitted by the MAH in a given calendar year.

Method of the payment:

On the basis of the call issued by the Institute, MAHs will be asked to pay the fee. The call will include the list of authorised products of individual MAHs and all the details of bank connection.

The payments for annual maintenance fee should be paid on an account number:

SK20 8180 0000 0070 0007 8053