



ÚSTAV ŠTÁTNEJ KONTROLY VETERINÁRNYCH BIOPREPARÁTOV A LIEČIV

Institute for State Control of Veterinary Biologicals and Medicaments

VETERINARY PREPARATIONS AND VETERINARY TECHNICAL DEVICES

ANNUAL MAINTENANCE FEE

for the costs of ÚŠKVBL related to ongoing regulatory supervision and other professional and administrative activities

In connection with the supervision and oversight of approved veterinary preparations and veterinary technical devices, which is carried out by the Institute for State Control of Veterinary Biologicals and Medicaments (hereinafter referred to as "ÚŠKVBL") pursuant to Act No. 17/2018 Coll. on veterinary preparations and veterinary technical devices and on amendments to certain laws, the holder of a decision on the approval of a veterinary preparation shall reimburse the ÚŠKVBL for the costs of its activities related to the duration of the approval of veterinary preparations in the form of annual maintenance fees.

The annual maintenance fee of €50 generally covers the costs of ongoing regulatory supervision of approved products and veterinary technical veterinary devices throughout their life cycle. The fee also covers other professional and administrative activities such as registers, provision of information, monitoring of adverse reactions and quality defects, statistics and management of lists, forms and the like.

The fee is payable by April 16 of the relevant year at the latest.

The annual maintenance fee for a veterinary product must be credited to the ÚŠKVBL account within 30 days of the date of delivery of the payment request; otherwise the fee will be increased by 20%.

No annual maintenance fee shall be payable for the calendar year in which the approval was granted. If the annual maintenance fee is paid for the calendar year in which the approval of the veterinary medicinal product is revoked or in the event of expiry of the approval, the proportional amount of the maintenance fee shall be refunded at the request of the holder of the approval decision. The holder of the approval decision must request a refund of the pro rata amount of the annual maintenance fee for the calendar year in question.

The method of payment of the fee and the fee refund request form are set out in separate documents.

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