



ÚSTAV ŠTÁTNEJ KONTROLY VETERINÁRNYCH BIOPREPARÁTOV A LIEČIV

Institute for State Control of Veterinary Biologicals and Medicaments

VETERINARY MEDICINAL PRODUCTS

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 registered veterinary medicinal products, which the State Institute for State Control of Veterinary Biologicals and Medicaments (hereinafter referred to as "ÚŠKVBL") continuously performs in accordance with Regulation (EU) 2019/6 on veterinary medicinal products and repealing Directive 2001/82/EC and Act 362/2011 Coll. on medicinal products and medical devices and amending certain acts (e.g. pursuant to Section 95(3) to (5), § 108, § 109, § 125(1) and § 134(2)(i) and (m)), the holder of a veterinary medicinal product registration decision shall reimburse the ÚŠKVBL for the costs of its activities related to the duration of the registration of veterinary medicinal products in the form of annual maintenance fees.

The annual maintenance fee of €300 generally covers the costs of ongoing regulatory supervision of veterinary medicinal products throughout their life cycle. The fee also covers other professional and administrative activities, such as maintaining the register, providing information on medicines, monitoring and re-evaluating adverse effects and quality defects in medicines, preparing guidelines, forms and applications, ATC classification, statistics on medicine consumption, etc.

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

The annual maintenance fee for veterinary medicinal products must be credited to the Institute's account no later than 30 days from the date of delivery of the request for payment; otherwise the fee shall be increased by 20%.

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

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

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