**ÚSKVBL/UST- 3/2006/Rev.4**

**Guideline of Institute for State Control of Veterinary Biologicals and Medicines**

**Administrative Fees for Actions Carried out on Request in Relation to Veterinary Non-medicinal Products and Veterinary Technical Devices**

**Date of the issue: 12.02.2024**

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**Amends the guideline: ÚSKVBL/UST - 3/2006/Rev.3**

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# 1. Introduction

This Guideline amends the rules for payment of administrative fees for actions carried out by the Institute for State Control of Veterinary Biologicals and Medicines (hereinafter referred to as the „Veterinary Institute“) on the basis of Act No. 634/2004 Coll., on Administrative Fees, as amended, in relation to veterinary non-medicinal products and veterinary technical devices. The current version of the Guideline ÚSKVBL/UST- 3/2006**/**Rev.3 has been revised due to the entry into force of Act No. 246/2022 Coll. on October 1, 2022 amending Act No. 166/1999 Coll., on Veterinary Care (hereinafter referred to as the “Veterinary Act”), as amended, and other related acts. As a result, the Annex to Act No. 634/2004 Coll., on Administrative Fees, was amended with regard to changes in administrative fees for veterinary non-medicinal products and veterinary technical devices. Previously, the payments were made for the act of approval/entry/variation/renewal and now they are made for the act of the submission of the application according to the Veterinary Act.

# 2. Aims and scope

The purpose of the guideline is to provide regulated subject with transparent rules for the payment of administrative fees in compliance with Act No. 634/2004 Coll., on Administrative Fees, as amended. The amounts of administrative fees are specified in the Annex of the Act (in „Scale of fees“) and, for clarity, the chargeable actions in connection with administrative proceedings carried on by the Veterinary Institute, incl. its amendments are attached to this Guideline as Annex 1.

# 3. The rules for administrative fees payment

**Administrative fees are to be paid prior to the submission of the application by a bank transfer to the following account:**

|  |  |
| --- | --- |
| Name of the bank | ČNB (CZECH NATIONAL BANK) |
| Account no | 19-31229641 |
| Bank code | 0710 |
| IBAN | CZ98 0710 0000 1900 3122 9641 |
| BIC (SWIFT) | CNBACZPP |
| Constant code | 1148 |
| Payment category | 355 - Research and development |

An applicant should attach a filled out administrative fee payment receipt (tax receipt) to the application for approval or to the application for entry of the veterinary technical device in two copies – see Annex No.2. After payment identification, the tax receipt will be confirmed and returned to the applicant. Together with the application, the applicant submits a copy of the bank statement (not the bank order) confirming that the administrative fee has been paid.

Each payment should be independent as a single payment order item so that it can be identified (do not pay multiple fees in a single payment).

Please note that the payment should be made in such a way that all bank charges are paid by the applicant so that the full amount defined by the Act on Administrative Fees is transferred to the Veterinary Institute account (see Annex No.1). For this purpose, the symbol “OUR” should be indicated on the payment order.

We would like to point out that if you transfer an amount lower than defined by the law to the Veterinary institute account, the administrative fee will not be considered paid.

Always quote the variable code, which is an eight-digit number.

* **The first two digits** identify: type of payment (see Annex No.1).
* **The next 4 digits** identify:
1. In case of applications for approval/entry of new veterinary (non-medicinal) product/veterinary technical device - application serial number\* and moth of payment
2. In other cases related to veterinary (non-medicinal) product quote the approval numbers before the hyphen
3. In other cases related to veterinary technical device quote the number before the slash (e.g. 003/08-C – indicate 003)
* **The last pair of digits** denotes the year of the payment.

|  |  |  |  |
| --- | --- | --- | --- |
| Ad **a)** | **Type of payment** | **Serial number and month of payment** | **Year of payment** |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **1** | **1** | **0** | **1** | **0** | **3** | **2** | **0** |

|  |  |  |  |
| --- | --- | --- | --- |
| Ad **b)** | **Type of payment** | **Approv. Number** | **Year of payment** |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **1** | **3** | **0** | **0** | **2** | **7** | **2** | **0** |

|  |  |  |  |
| --- | --- | --- | --- |
| Ad **c)** | **Type of payment** | **Register Number** | **Year of payment** |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **1** | **6** | **0** | **0** | **0** | **3** | **2** | **0** |

\*Serial number of the application: usually 1, if the applicant pays for several applications for an approval of new veterinary (non-medicinal) products, the payments are identified by increasing numbers (e.g. the first payment for a new application in March implies code 01, another payment for a new approval application in July implies code 02, etc.).

# 4. Links and related documents

Act No. [166/1999](https://www.zakonyprolidi.cz/cs/1999-166) Coll., on Veterinary Care and on Amendments to Certain Related Acts (Veterinary Act), as amended.

Act No. [634/2004](https://www.zakonyprolidi.cz/cs/2004-634) Coll., on Administrative Fees, as amended

# Annex No. 1 Administrative fees amounts

|  |  |  |
| --- | --- | --- |
| **Item 69**Application | **Variable****Code – Type of payment** | **Admin. fee** |
| **Acceptance of the Application for** |
| Approval of veterinary non-medicinal product and its entry in register of approved veterinary non-medicinal Products | 11 | 5.000,- |
| Entry of veterinary technical device in register of veterinary technical devices | 12 | 1.000,- |
| Variation to veterinary non-medicinal product approval licence of an administrative nature not requiring assessment  | 13 | 250,- |
| Variation to veterinary non-medicinal product approval licence requiring expert’s assessment | 14 | 1.000,- |
| Renewal of veterinary non-medicinal product approval licence | 15 | 1.000,- |
| Renewal of veterinary technical device entry in register of veterinary technical devices | 16 | 500,- |
| Variation to veterinary technical device entry in register of veterinary technical devices | 17 | 500,- |

# Annex No. 2 - Confirmation of administrative fee payment (for tax purposes)

INSTITUTE FOR STATE CONTROL OF VETERINARY BIOLOGICALS AND MEDICINES

 621 00 Brno, Hudcova 232/56a, Czech Republic

Tel.: +420 541 518 210, +420 541 518 211, E-mail:podatelna@uskvbl.cz

Acc. No.: 19-31229641/0710, Czech National Bank, payment title 355 - Research and development, IČO: 00019453

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**CONFIRMATION OF ADMINISTRATIVE FEE PAYMENT**

(TAX CERTIFICATE)

|  |  |  |
| --- | --- | --- |
| **Type of application** | **mark x** | **variable** **code – type of payment** |
| Approval of veterinary non-medicinal product and its entry in register of approved veterinary non-medicinal products |[ ]  11 |
| Entry of veterinary technical device in register of veterinary technical devices |[ ]  12 |
| Variation to veterinary non-medicinal product approval licence of an administrative nature not requiring assessment |[ ]  13 |
| Variation to veterinary non-medicinal product approval licence requiring expert’s assessment |[ ]  14 |
| Renewal of veterinary non-medicinal product approval licence |[ ]  15 |
| Renewal of veterinary technical device entry in register of veterinary technical devices |[ ]  16 |
| Variation to veterinary technical device entry in register of veterinary technical devices |[ ]  17 |
| **Applicant** - name, address:  |
| \* **Authorised person** - name, address, phone, fax, e-mail: |
| Product name: |
| Paid by bank transfer.Amount in CZK paid: ……………… On: ………….. |
| Account number of payer: | Variable code: | Constant code:1148 |

Date: Signature:

|  |
| --- |
| **PAYMENT RECEIPT CONFIRMATION**Paid by bank transfer - account number: Date of statement:  ----------------------------- ------------------------------------------------- Date On behalf of Marketing Authorisation Department Institute for State Control of Veterinary Biologicals and Medicines  |

**\* Note - In the space marked below, indicate your contact address to which this confirmation will be sent!**

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