**ÚSKVBL/UST-1/2025/Rev.2**

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

# Administrative fees and reimbursement of costs for expert tasks performed within the remit of the Institute for State Control of Veterinary Biologicals and Medicines

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## 1. Introduction

This guideline provides information regarding administrative fees and reimbursements of costs for expert tasks performed within the competence of ÚSKVBL. It contains comprehensive information and guidance following the legislative changes related to the implementation of the Regulation (EU) 2019/6 on veterinary medicinal products, the amendment to the Act on Pharmaceuticals No. 378/2007 Coll., the amendment to the Act No. 634/2004 Coll., on Administrative Fees, and the Act No. 349/2023 Coll., which, as of 1 January 2024, amends certain acts in connection with the consolidation of public budgets, including the Tax Code and the Act on Administrative Fees, specifically regarding the abolition of revenue stamps, i.e., the discontinuation of the possibility to pay administrative fees via revenue stamps.

The guideline regulates payments for tasks performed by the Institute for the State Control of Veterinary Biologicals and Medicines (ÚSKVBL) under the Act on Pharmaceuticals in connection with the applicability of Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products (hereinafter the "VMP Regulation") (direct applicability as of 28 January 2022).

The VMP Regulation has changed certain existing rules for the marketing authorisation of veterinary medicinal products and their post-authorisation procedures in the EU. While the said Regulation is directly applicable, in many respects it requires Member States to adopt implementing or adaptation rules, and in many instances, it allows Member States to establish their own regulatory conditions; this is also the case for the determination of administrative fees and reimbursements of costs for expert tasks in the field of veterinary medicinal products regulation.

The national adaptation regulation is the Act on Pharmaceuticals, whose adaptation amendment (Act No. 314/2022 of 12 October 2022) entered into force on 1 December 2022. This amendment also affected the scope of administrative fees as listed in the Act on Administrative Fees. Furthermore, amendments to the relevant implementing regulations (decrees) are and will be prepared.

One of the amendments to the implementing regulations, which was prepared and entered into force on **1 January 2026, is Decree No. 501/2025 Coll., of 28 November 2025, amending Decree No. 427/2008 Coll., on the determination of the amount of reimbursements of costs for expert tasks performed within the competence of the State Institute for Drug Control and the Institute for the State Control of Veterinary Biologicals and Medicines, as amended** (hereinafter the "Decree").

The Decree reflects the tasks that are in accordance with the above-described legal framework, including variations to marketing authorisations, the classification of which underwent the most significant substantive changes with the Regulation (more information on the classification of variations can be found in guideline ÚSKVBL/REG-1/2022, Information on the new rules for variations to marketing authorisations of veterinary products in connection with Regulation 2019/6, which is available on the ÚSKVBL website - Guidelines, and items that the current guideline already contained (e.g., reimbursement of costs in the field of residue determination, in the field of authorisation of the manufacture of transfusion products, biological veterinary medicinal products, radionuclide generators, in the field of registration of importers and distributors of active substances, and in the field of clinical trials).

However, there are also new items, such as:

- Annual maintenance fee for pharmacovigilance tasks and other tasks related to the duration of the marketing authorisation of veterinary medicinal products authorised by the European Commission, performed by the Institute for the State Control of Veterinary Biologicals and Medicines in accordance with the VMP Regulation,
- Application for the annual re-assessment of a marketing authorisation of a veterinary medicinal product granted under exceptional circumstances,
- Application for the five-year re-assessment of a marketing authorisation of a veterinary medicinal product granted for a limited market, and others.

The Decree adjusts the amounts of reimbursements of costs for tasks, which have generally increased. In determining these amounts, the inflation rate was primarily taken into account, and the costs associated with the necessary digitalisation of the ÚSKVBL system, resulting from the obligations imposed on the Institute by the VMP Regulation, were also reflected. For the reasons described above, it was necessary to update the existing guideline and issue this revision.

## 2. Objectives and Scope

The objective of this guideline is to provide regulated entities with detailed and transparent rules for the payment of individual types of fees required in accordance with the Act on Pharmaceuticals and related legal regulations.

The guideline thus covers the rules for the payment of:

- administrative fees;

  Based on the provisions of Act No. 634/2004 Coll., on Administrative Fees, as amended, administrative proceedings regulated by the Act on Pharmaceuticals are subject to administrative fees. The rules for the payment of administrative fees are set out in Act No. 634/2004 Coll. The amount of administrative fees is stipulated in the Annex to this Act (the "Tariff"), and for the sake of clarity, the fee-based tasks concerning administrative proceedings conducted by ÚSKVBL, which underwent adjustments as of 1 December 2022, are included in this guideline.

- reimbursements of costs for expert tasks performed upon request and for other expert tasks stipulated by the Act on Pharmaceuticals, which fall within the competence of ÚSKVBL;

  In accordance with Section 112 of the Act on Pharmaceuticals, ÚSKVBL collects reimbursements of costs for the performance of expert tasks upon request and for other expert tasks stipulated by this Act. The list of tasks subject to reimbursement of costs, the amount of such reimbursements, and the rules for the reduction or waiver of reimbursements are regulated by the Decree and this guideline, which takes into account the VMP Regulation. The definition of expert tasks performed by ÚSKVBL and the amounts of reimbursements of costs for their performance are set out in Annex No. 1 to this guideline (according to Annex No. 2 to the Decree).

- reimbursements of costs for ÚSKVBL tasks related to the duration of the marketing authorisation of medicinal products (annual maintenance fee);

  In accordance with Section 112(2) of the Act on Pharmaceuticals, the marketing authorisation holder shall further pay reimbursements of costs for ÚSKVBL tasks related to the duration of the marketing authorisation of veterinary medicinal products (concerning products authorised by the Institute) and for pharmacovigilance tasks (concerning products authorised by the European Commission) in the form of annual maintenance fees, such that the holder is obliged to pay the annual maintenance fee for the following calendar year by the end of the current calendar year. The amount of the maintenance fee is set out in Annex No. 1 to this guideline.

## 3. References and Related Documents

Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products (VMP Regulation).

Act No. 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended.

Decree No. 427/2008 Coll., on the determination of the amount of reimbursements of costs for expert tasks performed within the competence of the State Institute for Drug Control and the Institute for the State Control of Veterinary Biologicals and Medicines, as amended (as amended by Decree No. 501/2025 Coll. of 28 November 2025).

Commission Implementing Regulation (EU) 2021/17 establishing a list of variations not requiring assessment, as amended.

Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations (EMA/CMDv/7381/2021 of 9 September 2021, as amended), as amended.

Act No. 634/2004 Coll., on Administrative Fees, as amended.

Act No. 500/2004 Coll., Code of Administrative Procedure, as amended.

# 4. Rules for the Payment of Administrative Fees (Act No. 634/2004 Coll.)

## 4.1 Procedure for the Payment of Administrative Fees

The obligation to pay an administrative fee arises upon the receipt of applications or certain expert tasks (taking into account the necessity of updates to the Act on Administrative Fees, we only list items (codes) that fall within the remit of ÚSKVBL):

| Application/Procedure | CZK | Note |
|---|---|---|
| Code 69 | | |
| Application | | |
| - **for the issuance of a certificate** for a manufacturer of non-medicinal veterinary products - compliance with GMP requirements | **2000** | |
| Code 97 | | |
| Application | | |
| - **for marketing authorisation** of a veterinary medicinal product, including a traditional herbal veterinary medicinal product or a veterinary homeopathic product. | **2000** | |
| - **for variation** to the marketing authorisation, including a homeopathic product. | **2000** | |
| - **for transfer of the marketing authorisation** for a veterinary medicinal product, including a homeopathic product. | **2000** | |
| - **for authorisation of parallel trade** of a veterinary medicinal product, including a homeopathic product. | **2000** | |
| - **for withdrawal of the marketing authorisation** for a veterinary medicinal product, including a homeopathic product. | **1000** | |
| - **for the issuance of a decision** in cases of doubt as to whether a product is a veterinary medicinal product, a medicinal substance, a product subject to authorisation, or another type of product, including whether it is a veterinary homeopathic product. | **2000** | |
| - **for authorisation** of the marketing and use of a veterinary medicinal product not authorised in the EU or a third country **(Veterinary Special Treatment Programme)** | **2000** | |
| - **for authorisation of a clinical trial or** a confirmatory clinical trial of a veterinary medicinal product | **2000** | |
| Code 98 | | |
| Application | | |
| - for a manufacturing authorisation or a variation thereof for veterinary medicinal products and veterinary autogenous vaccines. | **2000** | |
| - for a manufacturing authorisation or a variations thereof for the manufacture of veterinary transfusion products or biological veterinary medicinal products. | **2000** | |
| - for an authorisation or a variation thereof for the activities of a control laboratory. | **2000** | |
| - for a manufacturing authorisation or a variation thereof for manufacturing in a transfusion service facility. | **2000** | |
| Code 99 | | |
| Application | | |
| - for a wholesale distribution authorisation or a variation thereof for veterinary medicinal products. | **2000** | |
| - for an extension of a wholesale distribution authorisation. | **2000** | |

| Code 3 | | |
|---|---|---|
| Issuance of a duplicate, transcript, copy, photocopy or an extract from official files, registers, records, documents, or other written and visual materials, including a statement of negative finding. | 50 CZK | per page or part thereof |
| | 30 CZK | for the first page |
| | and 10 CZK | for each subsequent page or part thereof, if produced using a photocopier or a computer printer. |

**Administrative fees shall be paid by bank transfer to an account maintained at the Czech National Bank.**

**A bank statement from the applicant's account confirming the execution of the respective administrative fee payment must be attached to the relevant application.**

If the applicant requires a confirmation of the administrative fee payment, they shall attach a completed form "Proof of Administrative Fee Payment" to the application, which can be found in Annex 2.

(Note: By Act No. 349/2023 Coll., amending certain acts in connection with the consolidation of public budgets, the Tax Code and the Act on Administrative Fees were amended as of 1 January 2024 to the effect of abolishing revenue stamps, effective from 1 January 2024. The Ministry of Finance will no longer issue or distribute any further revenue stamps. According to the transitional provision to the amendment of the Tax Code, if anyone held revenue stamps issued before this date, they could use them no later than 31 December 2024).

**ÚSKVBL details for the bank transfer of administrative fees:**

| | |
|---|---|
| Bank Name | ČNB (CZECH NATIONAL BANK) |
| Bank Address | Rooseveltova, 18<br>Brno<br>631 32<br>Czech Republic |
| Account Number | 19-31229641 |
| Bank Code | 0710 |
| IBAN | CZ98 0710 0000 1900 3122 9641 |
| BIC (formerly SWIFT) | CNBACZPP |
| Constant Symbol | 1148 |
| Variable Symbol | Generated as described below |
| Payment Title | 355-Research and development |

## 4.2. Obtaining a Variable Symbol for Administrative Fee Payment

The variable symbol differs in the case of:

- applications/tasks listed under Item 97 (see table in Section 4.1),
- applications/tasks listed under Item 69, 98, or 99, or under Item 3 (see table in Section 4.1).

**A. In the case of applications/tasks listed under ITEM 97,** the applicant shall obtain the variable symbol as follows:

- the variable symbol consists of **ten digits**,
- **the first digit** of the variable symbol is the number:
  - **5** (for tasks in the field of clinical trials) or
  - **1** (for all other tasks under Item 97 concerning the field of marketing authorisation),
- **the next two digits** of the variable symbol represent the **Item number** from the Act on Administrative Fees, specifically:
  - **97** (see table in Section 4.1),

- **the next four digits:**
  - represent **the middle part of the marketing authorisation number** of the medicinal product;
  - in the case of products that **have not yet been authorised (e.g., an application for marketing authorisation), or in the case of clinical trials or decisions in cases of doubt, four zeros are used;**
  - **for a specific therapeutic programme**, the veterinarian shall insert the registered **four-digit number under which they are registered with the Chamber of Veterinary Surgeons** (if the CVS number is not available, four zeros are used).

  The number is always given as a four-digit number; therefore, for a product authorised under marketing authorisation number 96/047/01-C, the symbol 0047 is used (see the example below). In the case of a grouping of several authorisations held by the same holder, the middle part of the marketing authorisation number of the medicinal product listed first in the application shall be used.

- **the next digit represents the sequence number of the submitted application - usually 1** is used; in the event that the applicant pays for multiple applications concerning the same task or the same medicinal product within a single month, these payments are marked with incrementally increasing numbers (for example, the first payment for a variation to the authorisation of product A in May means using symbol 1, the next payment for a variation to the authorisation of product A in May means using symbol 2, etc.; in the event of more than 9 variations for the payment of the same task for the same product within one calendar month, the payment must be made in the following month). In the example below, 2 is shown, which means that the applicant is paying the second administrative fee for a variation to a decision for a product authorised under marketing authorisation number 0047 in May (05),

- **the last two digits of the variable symbol indicate the month in which the payment is made.**

| Scope - Marketing Authorisation | Action Code | MA No. - Middle Part/KVL Registration Number | | | | Payment Sequence No. | Month of Payment | |
|---|---|---|---|---|---|---|---|---|
| 1 | 9 | 7 | 0 | 0 | 4 | 7 | 2 | 0 | 5 |

OR

| Scope - Clinical Trials | Action Code | Clinical Trials | | | | Payment Sequence No. | Month of Payment | |
|---|---|---|---|---|---|---|---|---|
| 5 | 9 | 7 | 0 | 0 | 0 | 0 | 1 | 1 | 2 |

**In the recipient message field, always state the name of the product or preparation to which the payment relates, even for already authorised products where the middle part of the marketing authorisation (MA) number can be provided!!!**

(In the case of an administrative fee payment for a single application covering multiple marketing authorization numbers, state the name of the product listed first in the application.)

**B. For applications concerning actions listed under <u>ITEM 69, 98, 99, or 3</u>,** the applicant shall obtain the variable symbol as follows:

- The variable symbol **<u>consists of nine digits</u>.**
- **<u>The first digit</u>** of the variable symbol is:
  - **<u>2</u>** for the area of Inspection (manufacturing, distribution, control laboratories), or
  - **<u>9</u>** for the General area (administrative actions).
- **<u>The next two digits</u> represent the Item number** from the Act on Administrative Fees, specifically:
  - **69 or**
  - **<u>98 or</u>**
  - **<u>99 or</u>**
  - **<u>03 (the item is listed with a leading zero to ensure it is always a two-digit number).</u>**
- **<u>The next four digits</u> represent the day (01-31) and month (01-12) of the payment** (e.g., for a payment made on April 3rd, the symbol 0304 is used).
- **<u>The final two digits</u> represent the year of the payment** (e.g., for the year 2024, the symbol 24 is used).

The example below shows the variable symbol for an administrative fee related to an application for an authorisation or a variation of an authorisation for the distribution of veterinary medicinal products, paid on October 4, 2024:

| Scope - INS-2, GEN-9 | Action Code | Day + Month of Payment | | | | Year of Payment | |
|---|---|---|---|---|---|---|---|
| 2 | 9 | 9 | 0 | 4 | 1 | 0 | 2 | 4 |

**<u>4.3. Refund of Administrative Fees</u>**

Paid administrative fees may only be refunded for reasons set forth in Section 7 of Act No. 634/2004 Coll., on Administrative Fees, as amended.

If any of the statutory grounds for a refund of the administrative fee occur and the applicant submits a request for refund, the ÚSKVBL shall issue a decision on such request in accordance with Act No. 337/1992 Coll., on the Administration of Taxes and Fees, as amended.

To request a refund, we recommend using the form "Request for Refund of Administrative Fee" (Annex 4).

# 5. Rules for the Payment of Reimbursement of Costs for Expert Tasks

## 5.1. General Rules

Under Section 112 of the Act on Pharmaceuticals, ÚSKVBL collects reimbursement of costs for expert tasks performed within its scope of authority. **Reimbursement of costs shall be paid prior to the submission of the application via bank transfer to an account held at the Czech National Bank, in the amount specified in Annex 1.**

**A proof of payment (bank statement) shall be attached to the respective application.**

**ÚSKVBL bank transfer details for the reimbursement of costs for expert tasks:**

| | |
|---|---|
| Bank Name | ČNB (CZECH NATIONAL BANK) |
| Bank Address | Rooseveltova, 18<br>Brno<br>631 32<br>Czech Republic |
| Account Number | 35-31229641 |
| Bank Code | 0710 |
| IBAN | CZ76 0710 0000 3500 3122 9641 |
| BIC (formerly SWIFT) | CNBACZPP |
| Constant Symbol | 1148 |
| Variable Symbol | Generated as described below |
| Payment Title | 355 - Research and Development |

To ensure that individual payments can be easily and uniquely assigned to specific applications, **a variable symbol generated for each application category using the procedure described below** shall be used to prevent any duplication of the variable symbol. We also recommend stating the name of the product (or, if not available, the requested task) to which the payment relates in the bank transfer note. In the case of a grouped application for multiple registration numbers, the name of the product listed first in the application shall be stated.

Cases in which payment is not required prior to the submission of the application and where a pre-generated variable symbol is sent to the applicant by ÚSKVBL are listed below in Sections 5.1.3 and 5.2.

**The Act on Pharmaceuticals allows for the reimbursement of costs to be collected in advance. Therefore, a bank statement from the applicant confirming that the respective payment has been made must be attached to the relevant application.**

Furthermore, a pre-filled document titled "**Confirmation of Payment of Reimbursement of Costs for Expert Tasks Performed within the Scope of ÚSKVBL**" must always be attached to all applications for expert tasks subject to reimbursement. This document is provided in Annex 3 of this guideline.

Once the payment has been identified on the aforementioned ÚSKVBL account, a confirmed copy of the document submitted with the application will be sent back to the applicant as a tax document.

**In the event that the applicant fails to submit the required documents, the application shall be assessed as incomplete.**

If an application is submitted at the beginning of the year, it is not advisable to make the payment in the preceding year.

**Applicants are advised that when paying the reimbursement of costs via bank transfer, bank transfer fees must be taken into account to ensure payment in the full amount and to avoid underpayments. The payment must be made in such a way that bank fees are covered by the applicant, ensuring that the full amount corresponding to the set administrative fee or reimbursement of costs for the given task-**as stated in the document "Confirmation of Payment of Reimbursement of Costs for Expert Tasks Performed within the Scope of ÚSKVBL" depending on the type of application-is transferred to the ÚSKVBL account. For this purpose, the "OUR" instruction must be specified on the payment order.

**We emphasize that if an amount lower than that specified in the tariff is transferred to the aforementioned ÚSKVBL account, the reimbursement of costs will not be considered paid until it has been paid in full.**

**Each payment for a respective application must be made separately as a single payment order item to enable unique identification of the payment; therefore, it is not possible to pay multiple reimbursements of costs (for several submitted applications) as one aggregate amount.** The reason for separating individual payments for a single applicant is the need to process each application entirely independently, ensuring that any potential payment issues with one application do not block other applications.

Furthermore, unused or erroneously sent payments or overpayments cannot be transferred from one application to another. In such cases, the applicant shall request a refund of the reimbursement of costs using the form in Annex 5, and these payments will be refunded.

**In the case of a grouping of variations for one or more marketing authorisations held by the same holder in a single application, the applicant shall pay one consolidated amount for all requested variations in the application.**

The amounts of reimbursement of costs for the Mutual Recognition Procedure (MRP) and the Decentralised Procedure (DCP) are identical, regardless of whether the Czech Republic is the Reference Member State (RMS) or a Concerned Member State (CMS).

**Applicants are advised to ensure that both administrative fees and reimbursements of costs are remitted to the correct accounts and in the correct amounts.**

#### 5.1.1. Reimbursement of Costs for Expert Tasks for Variation Applications via Worksharing

In the case of applications for variations requiring assessment (VRA - classification codes E, F, G, H) where the worksharing principle is applied and the application includes one or more different VRA variations, the reimbursement of costs for expert tasks shall be paid as follows:

- For each included variation, the amount required for the given type of variation shall be paid with regard to the timetable (R/S/E), regardless of the fact that for applications submitted via worksharing principle, a standard timetable is most commonly used.

The amounts of reimbursement of costs for national marketing authorisations included in international procedures (MRP) within worksharing are governed by the tariff for international procedures, distinguishing whether the Czech Republic acts as the Reference Member State (RMS) or a Concerned Member State (CMS).

#### 5.1.2. Variations to Marketing Authorisations Related to the Detailed Description of the Pharmacovigilance System

In the case of variations to marketing authorisations related to the detailed description of the pharmacovigilance system or the risk management system established by the marketing authorisation holder, the reimbursement of costs shall be paid in the amount corresponding to the type of variation as set forth in Commission Implementing Regulation (EU) 2021/17 or the CMDv Best Practice Guide on the classification of variations requiring assessment.

#### 5.1.3. Amount of Reimbursement of Costs for Expert Tasks Not Listed in Annex 2 to Decree No. 427/2008 Coll. (as amended by Decree No. 501/2025 Coll.), or where the Required Method is Not Specified

The amount of reimbursement of costs for expert tasks not listed in Annex 2 to the Decree, or for which the required method is not specified, shall be determined according to the formula set out in Annex 3 to said Decree. This calculation formula is used to determine the amount of the fee.

This calculation formula is used, for example, for written consultations, ÚSKVBL opinions provided upon request, and other cases.

**Calculation Formula**

Amount of reimbursement of costs (in CZK) = x * b
where:
x = number of working hours (each hour started)
b = costs per 1 hour of work, including wage costs, costs of materials, services, and domestic travel expenses

(Note: the amount of costs ("b") is currently set at CZK 660; however, it may change within amendments to this regulation. For this reason, ÚSKVBL always informs the applicant of the current amount when requesting payment of the total sum).

The reimbursement of costs depends on the number of hours of expert work; therefore, in this case, payment in advance is not required, and the variable symbol is sent to the applicant together with information regarding the calculation of the amount.

## 5.2 Rules for Reimbursement of Costs for Additional Tasks – Additional Payments for Marketing Authorisation Procedures

In accordance with the tariff of reimbursement of costs (see Annex 1 to this guideline), additional tasks are subject to fees only in cases where applications are submitted that do not contain the data and documentation (registration dossier) corresponding to the applicable requirements.

This applies to applications for new marketing authorisations and variations to marketing authorisations (type S and E) conducted via the national procedure.

The additional payment is required only once during a single procedure, even if the application is supplemented multiple times in some cases. An exception is made for situations where the required supplementation is of a particularly large scale and therefore requires further thorough assessment. In these exceptional cases, ÚSKVBL may require repeated settlement of the additional payment.

The notification to make the additional payment, together with a pre-generated variable symbol for this payment, is in most cases part of the first request to supplement the application regarding the content of the registration dossier (not the request associated with the validation of the application). Proof of the additional payment shall be sent together with the supplementary documentation. In the covering letter, please state the reference number under which the application is maintained.

## 5.3. Obtaining a Variable Symbol for the Reimbursement of Costs Payment

The variable symbol differs in the case of:

- Applications concerning tasks in the field of marketing authorisation of veterinary medicinal products (see Annex 1, chapter MARKETING AUTHORISATION),
- Applications concerning inspections, laboratory activities, clinical trials, or general tasks (see Annex 1, chapters **INSPECTION/LABORATORY ANALYSIS, BATCH RELEASE/ DETERMINATION OF RESIDUES OF PHARMACOLOGICALLY ACTIVE SUBSTANCES IN BIOLOGICAL MATERIALS/CLINICAL TRIALS/ACTIVITIES WITHIN THE EUROPEAN UNION/ AND GENERAL).**

**A. In the case of applications concerning tasks in the field of MARKETING AUTHORISATION of veterinary medicinal products,** the applicant shall obtain the variable symbol for payment as follows:

- The variable symbol consists of **ten digits**.
- **The first digit** of the variable symbol is **1 (tasks in the field of marketing authorisation).**
- **The next two digits represent the task code (see Annex 1 - code for VarS purposes) -** e.g., 14 - application for transfer of marketing authorisation.

  **If the same basic task code has multiple variants (e.g., 17a, 17b, 17c), only the basic code (e.g., 17) is entered into the variable symbol position; in the case of a grouping of variations in a single application,**

**the code for the main - "highest" - variation from which the other variations derive shall be provided.**

**The next four digits represent the middle part of the marketing authorisation number of the medicinal product; in the case of products not yet authorised (e.g., an application for marketing authorisation), four zeros are used; the number is always provided as a four-digit code;** therefore, for a product authorised under registration number 96/047/01-C, the symbol 0047 is used (see the example below). In the case of a grouping of several marketing authorisations of the same holder, the middle part of the marketing authorisation number of the medicinal product listed first in the application shall be provided.

- **the next single digit represents the sequence number of the submitted application - usually, "1"** is used. In the event that an applicant pays for multiple applications concerning the same procedure and the same medicinal product within a single month, these payments are marked with sequentially increasing numbers (e.g., the first payment for a variation to the authorised product A in May is marked with "1", the second payment for a variation to the authorised product A in May is marked with "2", etc.). If there are more than 9 variations for the same procedure for the same product within one calendar month, the payment must be made in the following month (in the example below, "2" is shown, which means that in May - 05 - the applicant is paying for the second application - 2 - for a variation - 10 - to a product authorised under authorisation number 0047).
- **the last two digits of the variable symbol indicate the month in which the payment is made.**

| Scope - Marketing Authorisation | Action Code | MA No. - Middle Part | | | | Payment Sequence No. | Month of payment | |
|---|---|---|---|---|---|---|---|---|
| 1 | 1 | 0 | 0 | 0 | 4 | 7 | 2 | 0 | 5 |

**B. In the case of applications concerning procedures in the field of INSPECTION, LABORATORY ANALYSIS, BATCH RELEASE, CLINICAL TRIALS, DETERMINATION OF RESIDUES OF PHARMACOLOGICALLY ACTIVE SUBSTANCES IN BIOLOGICAL MATERIALS, ACTIVITIES WITHIN THE EUROPEAN UNION AND GENERAL PROCEDURES, the applicant shall obtain the variable symbol for payment as follows:**

- the variable symbol is **a nine-digit number**,
- **the first digit of the variable symbol is:**
  - **2** for procedures in the field of INSPECTION,
  - **3** for LABORATORY ANALYSIS and BATCH RELEASE,
  - **4** for DETERMINATION OF RESIDUES OF PHARMACOLOGICALLY ACTIVE SUBSTANCES IN BIOLOGICAL MATERIALS,
  - **5** for CLINICAL TRIALS,
  - **6** for ACTIVITIES WITHIN THE EUROPEAN UNION, and
  - **7** for GENERAL PROCEDURES;
- **the next two digits** of the variable symbol represent **the procedure code (see Annex 1 - Code for VarS purposes),**
- e.g., **04 in the field of INSPECTION** - Application for authorisation to manufacture veterinary medicinal products with an on-site inspection - for the scope of sterile veterinary medicinal products - one product distinct pharmaceutical form, or one production unit/line at one manufacturing site; **if the same basic code/item has multiple variants (e.g., 29a/b/c for laboratory analysis), only the basic code (e.g., 29) is entered into the variable symbol position,**
- **the next four digits represent the day (01-31) and the month (01-12) on which the payment is made (e.g., for a payment made on 3 April, the symbol "0304" is entered),**
- **the next two digits represent the year in which the payment is made (e.g., for the year 2024, the symbol "24" is entered).**

The example below shows a variable symbol for the reimbursement of costs associated with an application for an authorisation to manufacture veterinary medicinal products with an on-site inspection - for the scope of sterile veterinary medicinal products - one product-distinct pharmaceutical form, or one production unit/line at one manufacturing site (national authorisation for a manufacturer in the Czech Republic), made on 4 October 2024:

| Scope - INS-2, LAB-3, RESIDUES-4, CLIN-5, EU-6, GENERAL-7 | Action Code | Day + Month of Payment | | | | Year of Payment | |
|---|---|---|---|---|---|---|---|
| 2 | 0 | 4 | 0 | 4 | 1 | 0 | 2 | 4 |

In the case of applications for a GMP inspection in a third country*, the amount corresponding to the required type of inspection as specified in the price list (Annex 1) shall be paid in advance, and an agreement will be concluded with the applicant regarding the reimbursement of the inspector's travel expenses, consisting of:

- air travel to the location nearest to the inspection site in "economy" class for flights within Europe, and in "business" class for flights outside Europe;
- coverage of accommodation costs in a standard category hotel for the required number of days;
- subsistence and local transport costs in a daily amount determined by the relevant legislation in force at the time. The inspector's arrival at the inspection site is normally expected the day before the start of the inspection, with departure on the final day of the inspection or the following day.

In the case of **an application for laboratory analysis,** the applicant shall specify the testing specification (pharmacopoeial monograph, authorisation documentation) according to which the analysis is to be performed, or shall list the individual testing methods. The reimbursement, calculated by the applicant according to the individual items in the price list, shall be paid in advance. A breakdown of the individual items shall be submitted with the application. In the case of special testing methods requiring the purchase of reference standards or expensive chemicals or kits, where the ÚSKVBL expenses exceed the items in the price list, the Institute shall inform the applicant immediately after the submission of the application and notify them of the amount of the additional costs. The analysis will be performed after these costs have been agreed upon by the applicant.

## 5.4 Refund of Reimbursement of Costs

In accordance with Section 112(4) of the Act on Pharmaceuticals, ÚSKVBL shall refund the reimbursement of costs based on a signed application submitted to ÚSKVBL. The application form is provided in Annex 5 to this guideline.

ÚSKVBL shall refund the reimbursement of costs, or a part thereof, to the applicant in the following cases:

a) if the applicant has paid the reimbursement without being obliged to do so, ÚSKVBL shall refund the reimbursement in full,

b) if the proceedings or the requested professional task have not been initiated at all, ÚSKVBL shall refund the reimbursement in full,

c) if the applicant has paid an amount higher than that set for the given professional task, ÚSKVBL shall refund the difference between these amounts,

d) if the applicant has paid and ÚSKVBL subsequently waived the payment based on the applicant's additional justified request, ÚSKVBL shall refund the reimbursement in full,

e) if the administrative proceedings are terminated at the request of the applicant, or if a professional task not performed within administrative proceedings is ended at the request of the applicant, ÚSKVBL shall refund a proportional part of the paid reimbursement corresponding to the professional tasks that had not been

* In this context, it refers to states that are neither members of the EU nor the European Economic Area (EHP, EEA), and have not signed an accession agreement with the EU or a Mutual Recognition Agreement (MRA) regarding Good Manufacturing Practice (GMP) inspections. At the time of this guidance's issuance, functional MRAs are in place with Canada, Switzerland, New Zealand, and Australia.

performed by the time the proceedings were ended; if an assessment report has already been prepared, all professional tasks shall be considered as performed.

If the amount to be refunded by ÚSKVBL is less than 100 CZK, ÚSKVBL shall not refund the reimbursement or any part thereof.

### 5.5. Waiver and Reduction of Reimbursement of Costs

The rules for the waiver and reduction of costs are regulated by Section 4 of the Decree; specified below are cases particularly concerning the direct application of the Regulation on VMPs (2019/6) and the Act on Pharmaceuticals.

#### 5.5.1. Waiver of Reimbursement of Costs or a Part Thereof

Reimbursement of costs may be reduced or waived only upon request. If any of the statutory grounds are met in a given case, the applicant shall submit, together with the application for the professional task, a request for the reduction or waiver of the reimbursement of costs in the form of a cover letter, justified in accordance with the provisions of Section 112 of the Act on Pharmaceuticals.

a) ÚSKVBL shall waive, upon request, the reimbursement of costs or a part thereof (provisions of Section 4(4) of the Decree) in the case of tasks the performance of which is in the public interest or which may have particularly significant consequences for a wider circle of persons, especially in the case of professional tasks performed particularly in connection with measures during the outbreak of animal diseases or zoonoses, or as part of measures aimed at increasing the availability of veterinary medicinal products for limited markets as defined in Article 4(29) of the Regulation on Veterinary Medicinal Products.

b) ÚSKVBL shall waive, upon request, the reimbursement of costs or a part thereof (provisions of Section 4(3) of the Decree) in the case of professional tasks performed in connection with the assessment of an application for the authorisation of clinical trials of veterinary medicinal products and their subsequent variations, where the sponsor of the clinical trial is a university or the state through its organisational unit, and no manufacturers of medicinal products or persons commercially linked to them participate in the trial, and the trial does not serve to collect data for the authorisation procedure; the reimbursement of costs or a part thereof shall be waived.

c) ÚSKVBL shall, upon request, reduce the amount of reimbursement of costs by 75% in the case of applications further specified in Section 4(1) of the Decree, for a veterinary medicinal product (VMP) which, at the time of submission of the relevant application, meets the conditions set out in the European Commission guidelines for the application of Article 23 or Article 25 of the Regulation on VMPs, or the conditions set out in Section 30a of the Act on Pharmaceuticals for the application of the aforementioned Articles.

d) The rules for a 50% reduction in the reimbursement of costs in connection with the assessment of an application for a clinical trial and its subsequent variations for micro, small, and medium-sized enterprises are set out in Section 4(3) of the Decree.

e) For products authorised under Article 23 or 25 of the Regulation on VMPs, the annual maintenance fee rate specified in Annex 1 to the guideline, code U-001, shall be reduced by 75%;
for products authorised under Section 25(6) of the Act on Pharmaceuticals, the aforementioned fee shall not be charged.

f) For immunological veterinary medicinal products, the use of which is possible only on the basis of an authorisation from the State Veterinary Administration, the fee specified in Annex 1 to this guideline, code U-002, shall not be charged.

#### 5.5.2. Other Options for the Reduction of Reimbursement of Costs

**Reduction of Reimbursement of Costs for VNRA Variations**

For variations not requiring assessment according to Article 61(1) of the Regulation on VMPs (VNRA variations - classification codes A, B, C, D), the system of reduction of reimbursement of costs remains in place. To apply a reduction of reimbursement of costs for professional tasks, the following rules shall apply:

- In cases where making an entry into the Union Product Database (UPD) involves one identical variation to the authorisation for multiple authorisation numbers, the reimbursement of costs for the first authorisation number shall be paid in full; for all remaining authorisation numbers, the applicant may request a 50% reduction in the reimbursement of costs.
- In the case of a group of identical variations for multiple authorisation numbers, the reimbursement of costs for the first variation from the group of identical VNRA variations shall be paid in full; for all remaining variations from the group of identical variations, the applicant may request a 50% reduction in the reimbursement of costs.

In exceptional situations (particularly due to technical difficulties), this rule may also be applied when notifications for an identical variation/group of identical variations in the UPD are made separately for each authorisation number, but only if these submissions are made in short chronological succession (and can therefore be considered a technical grouping).

**Reduction of Reimbursement of Costs for VRA Variations**

In departure from the principle of charging the full amount of reimbursement of costs for professional tasks determined for individual types of **VRA** variations according to the timetable set for each classification code, a fee reduction is applied:

a) **for a variation designated as G.I.18.** This concerns a variation to the current template for SPC/labelling/package leaflet texts to version 9 (or newer versions). In accordance with Article 152(2) of the Regulation on VMPs, this variation should be submitted so that the change is completed and implemented on the packaging and package leaflet by 29 January 2027. While this variation has a standard timetable (S) set, ÚSKVBL has taken into account the volume of professional activities performed for this type of G.I.18 variation and adjusted the required amount of reimbursement of costs so that it corresponds to the amount for variations with a reduced timetable (**R**) (see also Annex 1).

b) **for a variation/variations to national authorisations of immunological veterinary medicinal products** in cases where the application (grouping) specifically includes a variation/variations in the field of active substance manufacture designated as **F.I.a.1** - change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance for a biological/immunological product, for several authorisations of the same holder.

The assessment of the aforementioned variation (grouping) requires a single evaluation of viral safety and/or TSE risk of the starting material/reagent/intermediate, and the variation has no further impact on the quality, safety, and efficacy of the finished product. If the applicant intends to submit the same variation(s) from category F.I.a.1 for multiple authorisations held by them, they should verify in advance whether the above-mentioned case applies and that ÚSKVBL agrees with their intention and the submission of a grouped application.

In such cases, the reimbursement of costs shall be paid as follows:

- one variation with a set standard timetable - S (from category F.I.a.1) for multiple authorisation numbers - for the first authorisation number, the reimbursement of costs shall be paid in full; for all remaining authorisation numbers, the applicant may request a reduction of the reimbursement to the amount corresponding to variations with a set reduced timetable - R.
- a group of identical variations with a set standard timetable - S (from category F.I.a.1) for multiple authorisation numbers - for the first authorisation number, the reimbursement of costs for all requested variations shall be paid in full. For all identical variations of the remaining authorisation numbers, the applicant may request a reduction of the reimbursement to the amount corresponding to variations with a set reduced timetable - R.

A reduction in the reimbursement of costs cannot be applied in cases where the complexity or scope of the activities performed by ÚSKVBL remains unchanged and only a simplification of the system for the applicant occurs.

# 6. Reimbursement of Costs for ÚSKVBL Tasks Associated with the Maintenance of Authorisations for Medicinal Products (Annual Maintenance Fees)

## 6.1. General Rules

In accordance with Section 112(2) of the Act on Pharmaceuticals, the marketing authorisation holder shall pay the reimbursement of costs for ÚSKVBL tasks associated with the maintenance of the authorisation of veterinary medicinal products in the form of annual maintenance fees.

The annual maintenance fee now also applies to veterinary medicinal products authorised by the European Commission, covering pharmacovigilance tasks and other tasks associated with the maintenance of the authorisation performed by ÚSKVBL in accordance with the Regulation on Veterinary Medicinal Products. Due to the differing identification of individual VMPs, a veterinary medicinal product for these purposes is considered to be the unit defined by the data field contained in the European Union database pursuant to Article 55(1) of the Regulation on Veterinary Medicinal Products - specifically, the permanent identifier listed under data field ID 3.1 in Annex III to Commission Implementing Regulation (EU) 2021/16.

Annual maintenance fees are paid such that, by the end of the calendar year, the holder is obliged to pay the annual maintenance fee for the following calendar year, pursuant to the aforementioned provision. This means, for example, that in 2025, the holder pays the fee for the year 2026.

If the marketing authorisation holder fails to fulfil the obligation to pay this fee within the prescribed period, ÚSKVBL shall issue a request for late payment. This payment is due within 15 days of the delivery of the request.

If the annual maintenance fee is not paid even within the period set for late payment, the marketing authorisation holder is obliged to pay the fee increased by 50%.

The maintenance fee is not charged for the calendar year in which the authorisation was granted.

If an annual maintenance fee has been paid for a calendar year in which the authorisation of a veterinary medicinal product is withdrawn (either on the initiative of ÚSKVBL or at the request of the marketing authorisation holder), a proportional part of the maintenance fee will be refunded upon the MA holder’s request (see Annex 5). The proportional part is calculated from the paid annual amount by determining the monthly rate (annual fee divided by 12) and multiplying it by the number of remaining months until the end of the year. The amount for the month in which the product's authorisation expired for the reasons stated above is not refunded (e.g., if a product's authorisation expires on 3 May, the part of the annual fee for the months of June to December will be refunded).

## 6.2. Payment Procedure

The actual payment of the annual maintenance fee is made by bank transfer to an account held at the Czech National Bank, in the amount specified in Annex 1.

**ÚSKVBL bank transfer details for annual maintenance fees:**

| | |
|---|---|
| Bank name | ČNB (CZECH NATIONAL BANK) |
| Bank address | Rooseveltova, 18<br>Brno<br>631 32<br>Czech Republic |
| Account number | 35-31229641 |
| Bank code | 0710 |
| IBAN | CZ76 0710 0000 3500 3122 9641 |
| BIC (formerly SWIFT) | CNBACZPP |
| Constant symbol | 1148 |
| Variable symbol | Generated as described below |
| Payment title | 355 - Research and development |

**The MA holder may use one of the following procedures when paying the annual maintenance fee:**

**A. Separate payment for each medicinal product**

In this case, the marketing authorisation holder shall obtain the variable symbol for the annual maintenance fee payment as follows:

- the variable symbol consists of **nine digits;**
- **the first 3 positions** of the variable symbol represent the **task code**, i.e., **001** (annual maintenance fee) - see Annex 1;
- **the next 4 positions** represent the **middle part of the authorisation number of the veterinary medicinal product.** The number is always entered as a four-digit code; therefore, in the case of a product authorised under number 96/0104/07-C, the symbol 0104 is used (see example below);
- **the last 2 positions** represent the year for which the relevant maintenance fee is being paid. For example, if the payment is made during 2024 for the year 2025, the digits "25" are used (see example below).

| Action Code | | | MA No. - Middle Part | | | | Year for which the payment is made | |
|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 1 | 0 | 1 | 0 | 4 | 2 | 5 |

**Upon making the payment, the holder shall immediately send to ÚSKVBL proof of payment (account statement) and a copy of the pre-filled form "Confirmation of payment of reimbursement of costs for professional tasks performed within the competence of ÚSKVBL / for tasks associated with the maintenance of the authorisation (annual maintenance fee)" according to Annex 3.**

**B. Bulk payment for all of the holder's medicinal products**

**This method of payment is only possible provided that the following rules are observed:**
After making the payment, a cover letter shall be sent immediately to **ÚSKVBL** providing information about the chosen bulk payment method, together with a list of the documents submitted, and any other relevant information for ÚSKVBL.

**The following documents shall be submitted with the cover letter:**

- **proof of payment** (account statement);
- **a copy of the pre-filled form "Confirmation of payment of reimbursement of costs for professional tasks performed within the competence of ÚSKVBL / for tasks associated with the maintenance of the authorisation (annual maintenance fee)" according to Annex 3;**
- **in tabular form, a list of all veterinary medicinal products for which the payment is intended, always specifying the name of the product, its authorisation number, and the name of the marketing authorisation holder.**

In this case, the marketing authorisation holder shall obtain the variable symbol for the **ANNUAL MAINTENANCE FEE** payment upon request from ÚSKVBL, specifically via the email address subrtova@uskvbl.cz, or it will be sent to he holder as part of an information letter regarding the obligation to pay for tasks associated with the maintenance of the authorisation.

**After verifying the payment and the data in the aforementioned pre-filled form, ÚSKVBL shall send the confirmed form back to the holder. The form confirmed in this manner serves as a tax document for the holder.**

Apart from the details specified above, the general rules set out in Section 5.1 of this guideline shall apply mutatis mutandis to the payment of annual maintenance fees.

**Instructions for payment and the construction of the variable symbol for the annual maintenance fee concerning veterinary medicinal products authorised by the European Commission (listed in Annex 1 to the guideline under code U-002) will be specified during 2026 in a new revision of this guideline.**

## 6.3. Refund of the Annual Maintenance Fee

The refund of the annual maintenance fee is governed by the rules set forth in Section 112(4) of Act No. 378/2007 Coll., as specified in Section **5.4.** of this guideline.

## Annex 1: Schedule of Reimbursement of Costs for Expert Tasks Performed within the Remit of ÚSKVBL

- ÚSKVBL expert tasks are not subject to reimbursement of costs if they are requested by other organisational units of the state.
- The provision of information of an administrative nature, which does not constitute expert tasks, is governed by Act No. 106/1999 Coll., on Free Access to Information, as amended.

| Variable Symbol Code | Category (Expert Task) | Amount of Cost Reimbursement |
|---|---|---|
| | **ANNUAL MAINTENANCE FEE** | |
| U - 001<br>**001** | Annual maintenance fee for veterinary medicinal products authorised by ÚSKVBL. | 8 800 CZK |
| U-002<br>**002** | Annual maintenance fee for pharmacovigilance and other expert tasks associated with the continued authorisation of veterinary medicinal products authorised by the European Commission, performed by ÚSKVBL in accordance with the Regulation on veterinary medicinal products. | 3 000 CZK |
| | **GENERAL** | |
| O - 01<br>**01** | Application for an oral consultation per hour or part thereof upon request (not related to a previously submitted application). | 3 500 CZK |
| O - 02<br>**02** | Application for a written expert opinion upon request on an issue related to the Remit of ÚSKVBL in the field of veterinary medicinal products. | 7 300 CZK |
| O - 03<br>**03** | Application for a decision, not related to a previously submitted application, on whether a product is a veterinary medicinal product, a medicinal substance, a product subject to marketing authorisation, or another type of product, including whether it is a homeopathic product. | 9 600 CZK |
| | **MARKETING AUTHORISATION** | |
| | **NATIONAL MARKETING AUTHORISATION** | |
| RN - 01<br>**01** | Application for **marketing authorisation** of a veterinary medicinal product - marketing authorisation based on **complete** experimental and/or literature data, including marketing authorisation of products with a combination of active substances - veterinary medicinal product for **more than two target animal species** (national marketing authorisation). | 150 000 CZK |
| RN-D - 51<br>**51** | Additional activities performed only in cases where the submitted application or documentation (marketing authorisation dossier) does not comply with applicable requirements. | 33 100 CZK |
| RN - 02<br>**02** | Application for **marketing authorisation** of a veterinary medicinal product - marketing authorisation based on **complete** experimental and/or literature data, including marketing authorisation of products with a combination of active substances - veterinary medicinal product for **max. two target animal species** (national marketing authorisation). | 115 700 CZK |
| RN-D - 52<br>**52** | Additional activities performed only in cases where the submitted application or documentation (marketing authorisation dossier) does not comply with applicable requirements. | 33 100 CZK |
| RN - 03<br>**03** | Application for marketing authorisation of a veterinary medicinal product - **generic application:** submitted on the basis of incomplete documentation with reference to the marketing authorisation of the original product after the expiration of data protection. | 70 700 CZK |

| Variable Symbol Code | Category (Expert Task) | Amount of Cost Reimbursement |
|---|---|---|
| RN-D - 53<br>**53** | Additional activities performed only in cases where the submitted application or documentation (marketing authorisation dossier) does not comply with applicable requirements. | 13 200 CZK |
| RN - 04<br>**04** | Application for marketing authorisation of a veterinary medicinal product - **hybrid application**: submitted on the basis of incomplete documentation with reference to the marketing authorisation of the original product after the expiration of data protection, in combination with the applicant's own data. | 102 500 CZK |
| RN-D - 54<br>**54** | Additional activities performed only in cases where the submitted application or documentation (marketing authorisation dossier) does not comply with applicable requirements. | 26 500 CZK |
| RN - 05<br>**05** | **Multiple application** for marketing authorisation of an identical veterinary medicinal product (**duplicate/copy**) - submitted under a different trade name and potentially for a different applicant/marketing authorisation holder. | 23 800 CZK |
| RN-D - 55<br>**55** | Additional activities performed only in cases where the submitted application or documentation (marketing authorisation dossier) does not comply with applicable requirements. | 6 615 CZK |
| RN - 06<br>**06** | Application for marketing authorisation of a veterinary medicinal product - submitted on the basis of **informed consent** from another marketing authorisation holder. | 23 800 CZK |
| RN-D - 56<br>**56** | Additional activities performed only in cases where the submitted application or documentation (marketing authorisation dossier) does not comply with applicable requirements. | 6 615 CZK |
| RN - 07<br>**07** | **Variations** classified under codes G.I.7, G.I.9, G.I.10, G.I.13, G.I.14, and Category I, including changes which, by their nature, constitute a new veterinary medicinal product under Czech legislation (e.g., addition of a new strength or pharmaceutical form) - **E (90).** | 42 900 CZK |
| RN-D - 57<br>**57** | Additional activities performed only in cases where the submitted application or documentation (marketing authorisation dossier) does not comply with applicable requirements. | 6 600 CZK |
| RN - 08<br>**08** | Application for marketing authorisation of a veterinary medicinal product - **homeopathic product** subject to a simplified marketing authorisation procedure. | 65 500 CZK |
| RN-D - 58<br>**58** | Additional activities performed only in cases where the submitted application or documentation (marketing authorisation dossier) does not comply with applicable requirements. | 13 200 CZK |
| RN - 10<br>**10** | **Variations** classified under codes E, F, G, H - **S (60)**, except for variation G.I.18. | 32 400 CZK |
| RN-D - 60<br>**60** | Additional activities performed only in cases where the submitted application or documentation (marketing authorisation dossier) does not comply with applicable requirements. | 6 600 CZK |
| RN - 11<br>**11** | **Variations not requiring assessment (VNRA)** - classified under codes A, B, C, D: Administrative variations, variations with minimal impact on the quality, safety, or efficacy of the veterinary medicinal product, and variations with minimal impact on the Summary of Product Characteristics, which do not require a detailed scientific assessment and are listed in Commission Implementing Regulation (EU) 2021/17. | 6 600 CZK |
| RN - 43<br>**43** | **Variations** classified under codes E, F, G, H - **R (30)**, and variation **G.I.18.** | 9 300 CZK |

| Variable Symbol Code | Category (Expert Task) | Amount of Cost Reimbursement |
|---|---|---|
| RN - 90<br>**90** | Application for the **annual re-assessment of a marketing authorisation for a veterinary medicinal product granted under exceptional circumstances.** | 9 300 CZK |
| RN - 93<br>**93** | Application for the **five-year re-assessment of a marketing authorisation for a veterinary medicinal product granted for a limited market.** | 9 300 CZK |
| RN - 14<br>**14** | Application for the **transfer of a marketing authorisation** to another marketing authorisation holder. | 6 600 CZK |
| R - 15<br>**15** | Application for the **withdrawal** of a marketing authorisation for a veterinary medicinal product - **without additional requirements.** | No fee required |
| RN - 16<br>**16** | Application for the **withdrawal** of a marketing authorisation for a veterinary medicinal product - **with a request for a sell-out period.** | 4 000 CZK |
| | **CZ AS A REFERENCE MEMBER STATE** | |
| RRMS/NR - 17a<br>**17a** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **marketing authorisation** based on full experimental and/or bibliographical data, including marketing authorisation of products with a combination of active substances. Cases where **the veterinary medicinal product is not authorised in the Czech Republic (Decentralised Procedure)** and where a **maximum of 5 CMS are involved.** | 267 000 CZK |
| RRMS/NR - 17b<br>**17b** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **marketing authorisation** based on full experimental and/or bibliographical data, including marketing authorisation of products with a combination of active substances. Cases where **the veterinary medicinal product is not authorised in the Czech Republic (Decentralised Procedure)** and where **6 - 15 CMS are involved.** | 306 450 CZK |
| RRMS/NR - 17c<br>**17c** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **marketing authorisation** based on full experimental and/or bibliographical data, including marketing authorisation of products with a combination of active substances. Cases where **the veterinary medicinal product is not authorised in the Czech Republic (Decentralised Procedure)** and where **more than 15 CMS are involved.** | 345 600 CZK |
| RRMS/NR-D-67<br>**67** | Additional activities performed only in cases where the submitted application or documentation (marketing authorisation dossier) does not comply with applicable requirements. | 33 100 CZK |
| RRMS/R - 18a<br>**18a** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **marketing authorisation** based on full experimental and/or bibliographical data, including marketing authorisation of products with a combination of active substances. Cases where **the veterinary medicinal product has a valid marketing authorisation in the Czech Republic (Mutual Recognition Procedure)** and where a **maximum of 5 CMS are involved.** | 145 400 CZK |
| RRMS/R - 18b<br>**18b** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **marketing authorisation** based on full experimental and/or bibliographical data, including marketing authorisation of products with a combination of active substances. Cases where **the veterinary medicinal product has a valid marketing authorisation in the Czech Republic (Mutual Recognition Procedure)** and where **6 - 15 CMS are involved.** | 184 900 CZK |

| Variable Symbol Code | Category (Expert Task) | Amount of Cost Reimbursement |
|---|---|---|
| RRMS/R - 18c **18c** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **marketing authorisation** based on full experimental and/or bibliographical data, including marketing authorisation of products with a combination of active substances. Cases where **the veterinary medicinal product has a valid marketing authorisation in the Czech Republic (Mutual Recognition Procedure)** and where **more than 15 CMS are involved.** | 224 800 CZK |
| RRMS/R-D - 68 **68** | Additional activities performed only in cases where the submitted application or documentation (marketing authorisation dossier) does not comply with applicable requirements. | 19 800 CZK |
| RRMS/NR - 19a **19a** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **marketing authorisation** based on an abridged application with reference to the marketing authorisation of a reference product after the expiry of the data protection period (**generic application**). Cases where **the veterinary medicinal product is not authorised in the Czech Republic (Decentralised Procedure)** and where a **maximum of 5 CMS are involved.** | 138 100 CZK |
| RRMS/NR - 19b **19b** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **marketing authorisation** based on an abridged application with reference to the marketing authorisation of a reference product after the expiry of the data protection period (**generic application**). Cases where **the veterinary medicinal product is not authorised in the Czech Republic (Decentralised Procedure)** and where **6 - 15 CMS are involved.** | 157 900 CZK |
| RRMS/NR - 19c **19c** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **marketing authorisation** based on an abridged application with reference to the marketing authorisation of a reference product after the expiry of the data protection period (**generic application**). Cases where **the veterinary medicinal product is not authorised in the Czech Republic (Decentralised Procedure)** and where **more than 15 CMS are involved.** | 177 800 CZK |
| RRMS/NR-D-69 **69** | Additional activities performed only in cases where the submitted application or documentation (marketing authorisation dossier) does not comply with applicable requirements. | 13 200 CZK |
| RRMS/R - 20a **20a** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **marketing authorisation** based on an abridged application with reference to the marketing authorisation of a reference product after the expiry of the data protection period (**generic application**). Cases where **the veterinary medicinal product has a valid marketing authorisation in the Czech Republic (Mutual Recognition Procedure)** and where a **maximum of 5 CMS are involved**. | 105 700 CZK |
| RRMS/R - 20b **20b** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **marketing authorisation** based on an abridged application with reference to the marketing authorisation of a reference product after the expiry of the data protection period (**generic application**). Cases where **the veterinary medicinal product has a valid marketing authorisation in the Czech Republic (Mutual Recognition Procedure)** and where **6–15 CMS are involved.** | 125 500 CZK |

| Variable Symbol Code | Category (Expert Task) | Amount of Cost Reimbursement |
|---|---|---|
| RRMS/R - 20c **20c** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **marketing authorisation** based on an abridged application with reference to the marketing authorisation of a reference product after the expiry of the data protection period (**generic application**). Cases where **the veterinary medicinal product has a valid marketing authorisation in the Czech Republic (Mutual Recognition Procedure)** and where **more than 15 CMS are involved.** | 145 400 CZK |
| RRMS/R-D - 70 **70** | Additional activities performed only in cases where the submitted application or documentation (marketing authorisation dossier) does not comply with applicable requirements. | 13 200 CZK |
| RRMS/NR - 21a **21a** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **hybrid marketing authorisation**, i.e. marketing authorisation based on an abridged application with reference to the marketing authorisation of a reference product after the expiry of the data protection period, combined with the submission of proprietary data. Cases where **the veterinary medicinal product is not authorised in the Czech Republic (Decentralised Procedure)** and where a **maximum of 5 CMS are involved.** | 185 800 CZK |
| RRMS/NR – 21b **21b** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **hybrid marketing authorisation**, i.e. marketing authorisation based on an abridged application with reference to the marketing authorisation of a reference product after the expiry of the data protection period, combined with the submission of proprietary data. Cases where **the veterinary medicinal product is not authorised in the Czech Republic (Decentralised Procedure)** and where **6 - 15 CMS are involved.** | 212 200 CZK |
| RRMS/NR - 21c **21c** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **hybrid marketing authorisation**, i.e. marketing authorisation based on an abridged application with reference to the marketing authorisation of a reference product after the expiry of the data protection period, combined with the submission of proprietary data. Cases where **the veterinary medicinal product is not authorised in the Czech Republic (Decentralised Procedure)** and where **more than 15 CMS are involved.** | 238 500 CZK |
| RRMS/NR-D-71 **71** | Additional activities performed only in cases where the submitted application or documentation (marketing authorisation dossier) does not comply with applicable requirements. | 26 500 CZK |
| RRMS/R - 22a **22a** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **hybrid marketing authorisation**, i.e. marketing authorisation based on an abridged application with reference to the marketing authorisation of a reference product after the expiry of the data protection period, combined with the submission of proprietary data. Cases where **the veterinary medicinal product has a valid marketing authorisation in the Czech Republic (Mutual Recognition Procedure)** and where a **maximum of 5 CMS are involved.** | 125 500 CZK |

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| RRMS/R - 22b<br>**22b** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **hybrid marketing authorisation**, i.e. marketing authorisation based on an abridged application with reference to the marketing authorisation of a reference product after the expiry of the data protection period, combined with the submission of proprietary data. Cases where **the veterinary medicinal product has a valid marketing authorisation in the Czech Republic (Mutual Recognition Procedure)** and where **6 - 15 CMS are involved.** | 152 010 CZK |
| RRMS/R - 22c<br>**22c** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **hybrid marketing authorisation**, i.e. marketing authorisation based on an abridged application with reference to the marketing authorisation of a reference product after the expiry of the data protection period, combined with the submission of proprietary data. Cases where **the veterinary medicinal product has a valid marketing authorisation in the Czech Republic (Mutual Recognition Procedure)** and where **more than 15 CMS are involved**. | 178 500 CZK |
| RRMS/R - 72<br>**72** | Additional activities performed only in cases where the submitted application or documentation (marketing authorisation dossier) does not comply with applicable requirements. | 19 800 CZK |
| RRMS/EX - 23a<br>**23a** | **Variations** to marketing authorisation designated by classification codes G.I.7, G.I.9, G.I.10, G.I.13, G.I.14, and I, including variations which, according to the Act on Pharmaceuticals, lead to the assignment of a separate marketing authorisation number, i.e., the addition of a strength or pharmaceutical form of a veterinary medicinal product - **E (90)**; a **maximum of 5 CMS are involved**. | 99 100 CZK |
| RRMS/EX - 23b<br>**23b** | **Variations** to marketing authorisation designated by classification codes G.I.7, G.I.9, G.I.10, G.I.13, G.I.14, and I, including variations which, according to the Act on Pharmaceuticals, lead to the assignment of a separate marketing authorisation number, i.e., the addition of a strength or pharmaceutical form of a veterinary medicinal product - **E (90)**; **6 - 15 CMS are involved.** | 118 900 CZK |
| RRMS/EX - 23c<br>**23c** | **Variations** to marketing authorisation designated by classification codes G.I.7, G.I.9, G.I.10, G.I.13, G.I.14, and I, including variations which, according to the Act on Pharmaceuticals, lead to the assignment of a separate marketing authorisation number, i.e., the addition of a strength or pharmaceutical form of a veterinary medicinal product - **E (90); more than 15 CMS are involved.** | 138 800 CZK |
| RRMS/EX-D-73<br>**73** | Additional activities performed only in cases where the submitted application or documentation (marketing authorisation dossier) does not comply with applicable requirements. | 9 900 CZK |
| RRMS/CC - 24a<br>**24a** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **multiple application** for marketing authorisation (MRP/DCP/SRP) of a completely identical veterinary medicinal product under a different name (repeated marketing authorisation of a veterinary medicinal product under a different name and potentially for another Marketing Authorisation Holder - **duplicate or copy**). Cases where a **maximum of 5 CMS are involved.** | 42 900 CZK |
| RRMS/CC - 24b<br>**24b** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **multiple application** for marketing authorisation (MRP/DCP/SRP) of a completely identical veterinary medicinal product under a different name (repeated marketing authorisation of a veterinary medicinal product under a different name and potentially for another Marketing Authorisation Holder - **duplicate or copy**). Cases where **6 - 15 CMS are involved.** | 56 200 CZK |

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| RRMS/CC - 24c<br>**24c** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **multiple application** for marketing authorisation (MRP/DCP/SRP) of a completely identical veterinary medicinal product under a different name (repeated marketing authorisation of a veterinary medicinal product under a different name and potentially for another Marketing Authorisation Holder - **duplicate or copy**). Cases where **more than 15 CMS are involved**. | 62 800 CZK |
| RRMS/RU - 25a<br>**25a** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **Subsequent Recognition Procedure** for a veterinary medicinal product already authorised via a Mutual Recognition Procedure, for a **maximum of 5 new CMS**. | 92 500 CZK |
| RRMS/RU - 25b<br>**25b** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **Subsequent Recognition Procedure** for a veterinary medicinal product already authorised via a Mutual Recognition Procedure, for **6 - 15 new CMS**. | 105 700 CZK |
| RRMS/RU - 25c<br>**25c** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - **Subsequent Recognition Procedure** for a veterinary medicinal product already authorised via a Mutual Recognition Procedure, for **more than 15 new CMS**. | 112 300 CZK |
| RRMS/NR - 29a<br>**29a** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - marketing authorisation (Mutual Recognition Procedure / Decentralised Procedure / Subsequent Recognition Procedure) submitted on the basis of **informed consent** from another Marketing Authorisation Holder. Cases where a **maximum of 5 CMS are involved.** Application according to **Article 21** of the Regulation on veterinary medicinal products. | 42 900 CZK |
| RRMS/NR - 29b<br>**29b** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - marketing authorisation (Mutual Recognition Procedure / Decentralised Procedure / Subsequent Recognition Procedure) submitted on the basis of **informed consent** from another Marketing Authorisation Holder. Cases where **6 - 15 CMS are involved**. Application according to **Article 21** of the Regulation on veterinary medicinal products. | 56 200 CZK |
| RRMS/NR - 29c<br>**29c** | Application for the initiation of a Mutual Recognition Procedure with the Czech Republic as Reference Member State - marketing authorisation (Mutual Recognition Procedure / Decentralised Procedure / Subsequent Recognition Procedure) submitted on the basis of **informed consent** from another Marketing Authorisation Holder. Cases where **more than 15 CMS are involved.** Application according to **Article 21** of the Regulation on veterinary medicinal products. | 62 800 CZK |
| RRMS/ZII - 26a<br>**26a** | **Variations** classified under codes E, F, G, H - **S (60),** except for variation G.I.18, **for up to 5 CMS.** | 38 300 CZK |
| RRMS/ZII - 26b<br>**26b** | **Variations** classified under codes E, F, G, H **- S (60),** except for variation G.I.18, **for 6 - 15 CMS.** | 41 600 CZK |
| RRMS/ZII - 26c<br>**26c** | **Variations** classified under codes E, F, G, H - **S (60),** except for variation G.I.18, **for more than 15 CMS.** | 45 000 CZK |
| RRMS/ZIB - 27<br>**27** | **Variations** classified under codes E, F, G, H - **R (30)**, and **variation G.I.18.** | 9 900 CZK |
| RRMS/ZIA - 28<br>**28** | Variations not requiring assessment (**VNRA**) classified under codes A, B, C, D. | 6 600 CZK |
| RRMS-91<br>**91** | Application for the **annual re-assessment of a marketing authorisation for a veterinary medicinal product granted under exceptional circumstances.** | 9 900 CZK |

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| RRMS-92<br>**92** | Application for the **five-year re-assessment of a marketing authorisation for a veterinary medicinal product granted for a limited market.** | 9 900 CZK |
| | **CZ AS A CONCERNED MEMBER STATE** | |
| RCMS - 30<br>**30** | Application for recognition of a marketing authorisation granted for a medicinal product by the competent authority of another Member State - **authorisation** based on **full experimental and/or bibliographical data**, including authorisation of products with a combination of active substances. | 126 900 CZK |
| RCMS - 31<br>**31** | Application for recognition of a marketing authorisation granted for a medicinal product by the competent authority of another Member State - authorisation submitted on the basis of incomplete documentation with reference to the authorisation of the original product after the expiry of the data protection period **(generic application).** | 70 700 CZK |
| RCMS - 32<br>**32** | Application for recognition of a marketing authorisation granted for a medicinal product by the competent authority of another Member State - **hybrid application**, i.e., an authorisation submitted on the basis of incomplete documentation with reference to the marketing authorisation of the original product after the expiry of the data protection period, in combination with the submission of own data. | 98 400 CZK |
| RCMS - 33<br>**33** | **Variations** to marketing authorisation designated by classification codes G.I.7, G.I.9, G.I.10, G.I.13, G.I.14, and I, including variations which, according to the Act on Pharmaceuticals, lead to the assignment of a separate marketing authorisation number for a veterinary medicinal product, i.e., the addition of a strength or pharmaceutical form of a veterinary medicinal product - **E (90).** | 58 900 CZK |
| RCMS - 34<br>**34** | Application for recognition of a marketing authorisation granted for a medicinal product by the competent authority of another Member State - **multiple application** for marketing authorisation of an identical veterinary medicinal product under a different name (repetition of a marketing authorisation under a different name and potentially for a different holder - duplicate or copy). | 35 600 CZK |
| RCMS - 38<br>**38** | Application for recognition of a marketing authorisation granted for a medicinal product by the competent authority of another Member State - authorisation submitted on the basis of the **informed consent** of another marketing authorisation holder. | 35 600 CZK |
| RCMS/ZII - 35<br>**35** | **Variations** classified under codes E, F, G, H - **S (60)**, except for variation G.I.18. | 32 400 CZK |
| RCMS/ZIB - 36<br>**36** | **Variations** classified under codes E, F, G, H - **R (30)**, and **variation G.I.18.** | 7 900 CZK |
| RCMS/ZIA - 37<br>**37** | Variations not requiring assessment (**VNRA**) classified under codes A, B, C, D. | 6 600 CZK |
| RCMS - 92<br>**92** | Application for the **annual re-assessment of a marketing authorisation for a veterinary medicinal product granted under exceptional circumstances.** | 7 900 CZK |
| RCMS - 95<br>**95** | Application for the **five-year re-assessment of a marketing authorisation for a veterinary medicinal product granted for a limited market.** | 7 900 CZK |
| | **PARALLEL TRADE** | |
| RSD - 39<br>**39** | Application for parallel trade approval for a veterinary medicinal product. | 43 600 CZK |
| RSD - 40<br>**40** | Application for the renewal of a parallel trade approval for a veterinary medicinal product. | 23 800 CZK |
| | **ISSUANCE OF A CERTIFICATE FOR A MEDICINAL PRODUCT** | |
| RC - 41<br>**41** | Application for the issuance of a Certificate of a Pharmaceutical Product for a veterinary medicinal product in accordance with the WHO Certification Scheme. | 2 300 CZK |

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| | **MARKETING AUTHORISATION OF VETERINARY MEDICINAL PRODUCTS OUTSIDE THE SCOPE OF THE REGULATION ON VETERINARY MEDICINAL PRODUCTS** | |
| RZ-42<br>**42** | Marketing authorisation of a veterinary medicinal product according to Section 25(6)(a) of the Act on Pharmaceuticals, intended exclusively for pet animals: aquarium animals, animals kept in garden ponds, ornamental birds, racing pigeons, terrarium animals, small rodents, ferrets, and rabbits, provided that such products are not subject to a veterinary prescription. | 5 000 CZK |
| RZ-43<br>**43** | Variation to a marketing authorisation of type VNRA concerning a medicinal product according to Section 25(6)(a) of the Act on Pharmaceuticals, intended exclusively for pet animals: aquarium animals, animals kept in garden ponds, ornamental birds, racing pigeons, terrarium animals, small rodents, ferrets, and rabbits, provided that such products are not subject to a veterinary prescription. | 500 CZK |
| RZ-44<br>**44** | Variation to a marketing authorisation other than type VNRA concerning a medicinal product according to Section 25(6)(a) of the Act on Pharmaceuticals, intended exclusively for pet animals: aquarium animals, animals kept in garden ponds, ornamental birds, racing pigeons, terrarium animals, small rodents, ferrets, and rabbits, provided that such products are not subject to a veterinary prescription. | 1 000 CZK |
| RZ-45<br>**45** | Marketing authorisation of a traditional herbal veterinary medicinal product according to Section 25(6)(b) of the Act on Pharmaceuticals. | 5 000 CZK |
| RZ-46<br>**46** | Variation to a marketing authorisation of type VNRA concerning a traditional herbal veterinary medicinal product according to Section 25(6)(b) of the Act on Pharmaceuticals. | 500 CZK |
| RZ-47<br>**47** | Variation to a marketing authorisation other than type VNRA concerning a traditional herbal veterinary medicinal product according to Section 25(6)(b) of the Act on Pharmaceuticals. | 1 000 CZK |
| RZ-48<br>**48** | Marketing authorisation of a veterinary radiopharmaceutical according to Section 25(6)(c) of the Act on Pharmaceuticals. | 5 000 CZK |
| RZ-49<br>**49** | Variation to a marketing authorisation of type VNRA concerning a veterinary radiopharmaceutical according to Section 25(6)(c) of the Act on Pharmaceuticals. | 500 CZK |
| RZ-50<br>**50** | Variation to a marketing authorisation other than type VNRA concerning a veterinary radiopharmaceutical according to Section 25(6)(c) of the Act on Pharmaceuticals. | 1 000 CZK |
| | **INSPECTION** | |
| | **MANUFACTURE OF VETERINARY MEDICINAL PRODUCTS** | |
| I - 01<br>**01** | Application for a manufacturing authorisation for veterinary medicinal products or for a variation to an authorisation - for the scope of imports from third countries. | 23 900 CZK |
| I - 02<br>**02** | Application for a manufacturing authorisation for veterinary medicinal products (including veterinary autogenous vaccines) - for a range of non-sterile medicinal products - one dissimilar pharmaceutical form or one production unit/line at a single manufacturing site. | 36 300 CZK |
| I - 03<br>**03** | Application for a manufacturing authorisation for veterinary medicinal products (including veterinary autogenous vaccines) or for a variation to an authorisation - for a range of non-sterile medicinal products - any additional distinct pharmaceutical form and/or production unit/line. | 18 200 CZK |

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| I - 04<br>**04** | Application for a manufacturing authorisation for veterinary medicinal products (including veterinary autogenous vaccines) - for a range of sterile medicinal products - one dissimilar pharmaceutical form or one production unit/line at a single manufacturing site. | 57 900 CZK |
| I - 05<br>**05** | Application for a manufacturing authorisation for veterinary medicinal products (including veterinary autogenous vaccines) or for a variation to an authorisation - for a range of sterile medicinal products - any additional dissimilar pharmaceutical form or production unit/line. | 26 730 CZK |
| I - 06<br>**06** | Application for a variation to a manufacturing authorisation for veterinary medicinal products (including veterinary autogenous vaccines) - addition of a manufacturer's warehouse. | 11 300 CZK |
| I - 07<br>**07** | An increase in the basic fee in cases involving the biotechnological or technologically demanding manufacture of veterinary medicinal products of biological origin. | 32 900 CZK |
| I - 08<br>**08** | Application for a manufacturing authorisation for veterinary medicinal products - for a range of self-packaged primary packaging of non-sterile products (including veterinary autogenous vaccines) - one different pharmaceutical form and/or one production unit/line at a single manufacturing site. | 28 300 CZK |
| I - 09<br>**09** | Application for a manufacturing authorisation for veterinary medicinal products or for a variation to an authorisation - for the scope of a self-contained primary packaging of non-sterile products (including veterinary autogenous vaccines) - any additional distinct pharmaceutical form and/or production unit/line. | 14 200 CZK |
| I - 10<br>**10** | Application for a manufacturing authorisation for veterinary medicinal products (including veterinary autogenous vaccines) - for a range of self-contained secondary packaging at a single manufacturing site. | 24 400 CZK |
| I - 11<br>**11** | An application for a manufacturing authorisation for veterinary medicinal products (including veterinary autogenous vaccines) or for a variation to an authorisation - for a range of secondary packaging of non-sterile products carried out separately - of each additional manufacturing site. | 12 000 CZK |
| I - 12<br>**12** | Application for a variation to a manufacturing authorisation for veterinary medicinal products (including veterinary autogenous vaccines) - without a manufacturing site inspection. | 3 900 CZK |
| I - 13<br>**13** | Application for a manufacturing authorisation exclusively for veterinary transfusion products within the meaning of Section 68a of the Medicines Act - for one manufacturing site. | 13 500 CZK |
| I - 14<br>**14** | Application for a manufacturing authorisation exclusively for veterinary transfusion products within the meaning of Section 68a of the Medicines Act or for a variation to an authorisation - for each additional manufacturing site. | 6 500 CZK |
| I - 15<br>**15** | Application for a variation to a manufacturing authorisation exclusively for transfusion products within the meaning of Section 68a of the Medicines Act - without an inspection at the manufacturing site. | 2 800 CZK |
| I - 16<br>**16** | Application for a manufacturing authorisation exclusively for biological veterinary medicinal products within the meaning of Section 68c of the Medicines Act - for a single manufacturing site. | 13 500 CZK |
| I - 17<br>**17** | Application for a manufacturing authorisation exclusively for biological veterinary medicinal products within the meaning of Section 68c of the Medicines Act or for a variation to an authorisation - for each additional manufacturing site. | 6 500 CZK |

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| I - 18<br>**18** | Application for a variation to a manufacturing authorisation for exclusively biological veterinary medicinal products within the meaning of Section 68c of the Medicines Act - without inspection at the manufacturing site. | 2 800 CZK |
| I - 19<br>**19** | Application for a manufacturing authorisation for exclusively veterinary radiopharmaceuticals authorised under Section 25(6)(c) of the Medicines Act - for a single manufacturing site. | 8 000 CZK |
| I - 20<br>**20** | Application for a manufacturing authorisation for exclusively veterinary radiopharmaceuticals authorised under Section 25(6)(c) of the Medicines Act or for a variation to an authorisation - for each additional manufacturing site. | 4 000 CZK |
| I - 21<br>**21** | Application for a variation to a manufacturing authorisation for exclusively veterinary radiopharmaceuticals authorised under Section 25(6)(c) of the Medicines Act - without inspection at the manufacturing site. | 1 500 CZK |
| I - 22<br>**22** | Application for a manufacturing authorisation exclusively for veterinary medicinal products pursuant to Section 25(6)(a) of the Medicines Act, intended only for companion animals, which are aquarium animals, animals kept in garden ponds, ornamental birds, racing pigeons, terrarium animals, small rodents, ferrets and rabbits, unless their supply is subject to a veterinary prescription - for a single place of production. | 8 000 CZK |
| I - 23<br>**23** | Application for a manufacturing authorisation exclusively for veterinary medicinal products pursuant to Section 25(6)(a) of the Medicines Act, intended only for companion animals, which are aquarium animals, animals kept in garden ponds, ornamental birds, racing pigeons, terrarium animals, small rodents, ferrets and rabbits, unless their supply is subject to a veterinary prescription or a variation to the authorisation - for each additional manufacturing site. | 4 000 CZK |
| I - 24<br>**24** | Application for a variation to a manufacturing authorisation exclusively for veterinary medicinal products pursuant to Section 25(6)(a) of the Medicines Act, intended only for companion animals, which are aquarium animals, animals kept in garden ponds, ornamental birds, racing pigeons, terrarium animals, small rodents, ferrets and rabbits, unless their supply is subject to a veterinary prescription - without inspection at the manufacturing site. | 1 500 CZK |
| I - 25<br>**25** | Application for a manufacturing authorisation exclusively for traditional herbal veterinary medicinal products authorised under Section 25(6)(b) of the Medicines Act - for a single manufacturing site. | 8 000 CZK |
| I - 26<br>**26** | Application for a manufacturing authorisation exclusively for traditional herbal veterinary medicinal products authorised under Section 25(6)(b) of the Medicines Act or for a variation to an authorisation - for each additional manufacturing site. | 4 000 CZK |
| I - 27<br>**27** | Application for a variation to a manufacturing authorisation exclusively for traditional herbal veterinary medicinal products authorised pursuant to Section 25(6)(c) of the Medicines Act - without inspection at the manufacturing site. | 1 500 CZK |
| | **DISTRIBUTION OF VETERINARY MEDICINES** | |
| I - 28<br>**28** | Application for an authorisation for wholesale distribution of veterinary medicinal products or for a variation to an authorisation - with the inspection of one warehouse. | 23 400 CZK |
| I - 29<br>**29** | Application for an authorisation for wholesale distribution of veterinary medicinal products or for a variation to an authorisation - each additional warehouse within one application. | 11 300 CZK |
| I - 30<br>**30** | Application for extension of an authorisation for wholesale distribution of veterinary medicinal products for the distribution of active substances, excipients - with the inspection of one warehouse. | 15 400 CZK |

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| I - 31<br>**31** | Application for extension of an authorisation for wholesale distribution of veterinary medicinal products for the distribution of active substances, excipients - each additional warehouse under one authorisation. | 11 300 CZK |
| I - 32<br>**32** | Application for a variation to an authorisation for wholesale distribution of veterinary medicinal products - without inspection. | 3 900 CZK |
| | **CONTROL OF VETERINARY MEDICINAL PRODUCTS** | |
| I - 33<br>**33** | Application for a manufacturing authorisation for veterinary medicinal products - for the scope of independently performed quality control or for a variation to an authorisation - performance of partial tests - at one control site. | 22 700 CZK |
| I - 34<br>**34** | Application for a manufacturing authorisation for veterinary medicinal products - for the scope of independently performed quality control or for a variation to an authorisation - comprehensive testing (physically chemical, microbiological and biological testing) - at one control site. | 30 600 CZK |
| I - 35<br>**35** | Application for a manufacturing authorisation for veterinary medicinal products - for the scope of independently performed quality control or for a variation to an authorisation - each additional control site. | 11 600 CZK |
| I - 36<br>**36** | Application for a variation to a manufacturing authorisation for veterinary medicinal products - for the scope of independently performed quality control - without inspection at the control site. | 3 900 CZK |
| | **GMP COMPLIANCE CERTIFICATION(S), REVOCATION OF AN AUTHORISATION TO OPERATE ON REQUEST, APPLICATION FOR GMP COMPLIANCE CERTIFICATE OF A FOREIGN MANUFACTURER** | |
| I - 40<br>**40** | Application for the issue of a certificate of compliance with the conditions of good manufacturing practice or good distribution practice to holders of relevant authorisations and registrations. | 1 800 CZK |
| I - 41<br>**41** | Application for the issue of a certificate of compliance with the conditions of good manufacturing practice in the manufacture of active substances - one production unit/line. | 37 500 CZK |
| I - 42<br>**42** | Application for the issue of a certificate of compliance with the conditions of good manufacturing practice in the manufacture of active substances - each additional manufacturing unit/line. | 17 600 CZK |
| I - 43<br>**43** | Application for revocation of an authorisation to operate. | No fee required |
| I - 44<br>**44** | Application for a certificate of compliance with the requirements of good manufacturing practice with inspection of a foreign manufacturer (‘certificate’) pursuant to Section 16(2)(a)(3) of the Medicines Act. | Reimbursement per type of inspection requested plus 50 % + reimbursement of travel and subsistence expenses |
| | **LABORATORY TESTING, BATCH RELEASE** | |
| L - 01<br>**01** | Batch release of immunological veterinary medicinal product based on control testing in the Official Medicines Control Laboratory (OCABR) - with the submission of a certificate from a Member State of the European Union. | 700 CZK |
| L - 02<br>**02** | Batch release of immunological veterinary medicinal product based on control testing in the Official Medicines Control Laboratory (OCABR) - without the submission of a certificate from a Member State of the European Union. | 2 000 CZK<br>+<br>Reimbursement per type of used methods |

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| L - 03<br>**03** | Batch release of immunological veterinary medicinal product based on evaluation of the batch documentation (control reports), without laboratory testing (OBPR) - with the submission of a certificate from a Member State of the European Union. | 700 CZK |
| L - 04<br>**04** | Batch release of immunological veterinary medicinal product based on evaluation of the batch documentation (control reports), without laboratory testing (OBPR) - without the submission of a certificate from a Member State of the European Union. | 2 000 CZK |
| L - 05<br>**05** | Laboratory testing on request. | Reimbursement per type of used methods |
| | **DETERMINATION OF PHARMACOLOGICALLY ACTIVE SUBSTANCES IN BIOLOGICAL MATRIXES** | |
| M - 01 | Determination of residues in complex matrix by liquid chromatomatography with mass spectrometry detection (LC-MS/MS). | 7 300 CZK |
| M - 02 | Determination of residues in complex matrix by gas chromatomatography with mass spectrometry detection (GC-MS or GC-MS/MS). | 8 000 CZK |
| | **CLINICAL TRIALS** | |
| K - 01<br>**01** | Application for clinical trial authorisation of a veterinary medicinal product. | 28 200 CZK |
| K - 02<br>**02** | Application for a variation of the terms of a clinical trial of a veterinary medicinal product. | 9 300 CZK |
| K - 03<br>**03** | Application for confirmatory clinical trial authorisation of a veterinary medicinal product. | 75 900 CZK |
| K - 04<br>**04** | Application for a variation of the terms of a confirmatory clinical trial of a veterinary medicinal product. | 6 900 CZK |
| K - 05<br>**05** | Application for approval of a non-interventional post-authorisation veterinary study. | No fee required |
| K - 06<br>**06** | Application for a variation of an approved non-interventional post-authorisation veterinary study. | No fee required |
| | **EU-LEVEL ACTIVITIES** | |
| E - 01<br>**01** | Request for the performance of scientific tasks submitted by the European Medicines Agency (EMA).* | In accordance with the contractual agreement between the Veterinary Institute and the EMA, and with the terms set out in the directly applicable European Union regulation.* |
| E - 02<br>**02** | Scientific tasks performed at the request of the European Directorate for the Quality of Medicines & HealthCare (EDQM). | In accordance with the contractual agreement between the Veterinary Institute and the EDQM. |

* Regulation (EU) 2024/568 of the European Parliament and of the Council on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95.

**Schedule of reimbursement of costs for laboratory analyses of medicines and excipients performed within the remit of ÚSKVBL**

| Item | Test | Amount of Cost Reimbursement |
|---|---|---|
| | **PHYSICOCHEMICAL TESTS** | |
| 1 | Appearance | 590 CZK |
| 2 | Determination of particle size | |
| 2a | *By microscopy* | 2 400 CZK |
| 2b | *By sieve test - 1 sieve* | 1 870 CZK |
| 2c | for each additional sieve, add to item 2b | 380 CZK |
| 3 | Airtightness | 390 CZK |
| 4 | Determination of solubility | 710 CZK |
| 5 | Loss on drying | 2 920 CZK |
| 6 | Karl-Fisher titration | 3 720 CZK |
| 7 | Residue on evaporation | 1 490 CZK |
| 8 | Ash | |
| 8a | *Total ash* | 3 220 CZK |
| 8b | *Sulfated ash or other complex method* | 3 800 CZK |
| 9 | Instrumental determination of melting point | 1 140 CZK |
| 10 | Density | |
| 10a | *Pycnometer* | 1 340 CZK |
| 10b | *Densitometer* | 1 340 CZK |
| 11 | Viscosity determination using a rotational viscometer | 2 150 CZK |
| 12 | Refractive index | 1 320 CZK |
| 13 | Spectrophotometric determination | 5 290 CZK |
| 14 | Titration | 2 950 CZK |
| 15 | pH determination | 1 030 CZK |
| 16 | Conductivity | 1 030 CZK |
| 17 | Thin-layer chromatography | 4 760 CZK |
| 18 | Liguid chromatography (HPLC) | |
| 18a | *1 analyte* | 8 480 CZK |
| 18b | *1 analyte in two samples* | 10 640 CZK |
| 18c | *1 analyte in two or more samples - item increases by* | 2 200 CZK |
| 18d | *1 analyte - 3 samples* | 12 840 CZK |
| 18e | *1 analyte - 4 samples* | 15 040 CZK |
| 18f | *2 analytes in one determination* | 11 700 CZK |
| 18g | *3 and more analytes in one determination* | 15 030 CZK |
| 19 | Gas chromatography | 8 040 CZK |
| 20 | Colour and precipitation reactions | 1 040 CZK |
| 21 | Clarity and degree of opalescence of liquids (visual) | 1 570 CZK |
| 22 | Degree of coloration of liquids (visual) | 1 670 CZK |
| 23 | Determination of aktivity of pepsin | 8 170 CZK |
| 24 | Dissolution - UV/VIS | 8 810 CZK |
| 25 | Dissolution - HPLC | 9 750 CZK |
| 26 | Average weight and mass uniformity | 1 040 CZK |
| 27 | Resistence to crushing | 1 650 CZK |
| 28 | Identification reactions of ions and functional groups | 730 CZK |
| 29 | Desintegration of tablets | |
| 29a | *In water* | 2 460 CZK |
| 29b | *In simulated gastric fluid* | 2 910 CZK |

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| 29c | *In simulated intestinal fluid* | 3 010 CZK |
| 30 | Extractable volume of parenteral preparations | 1 160 CZK |
| 31 | Dimensions of dosage unit (instrumental) | 1 350 CZK |
| 32 | Dimensions of dosage units (calliper) | 1 020 CZK |
| 33 | Content uniformity | 12 770 CZK |
| | **MICROBIOLOGICAL AND BIOLOGICAL TESTS** | |
| 34 | Sterility testing | 9 570 CZK |
| 35 | Microbiological examination of non-sterile products (enumeration of total viable aerobic microorganisms) | |
| 35a | Microbiological examination of non-sterile products - preparations for local administration (cutaneous, nasal, ear administration, etc.) | 5 750 CZK |
| 35b | Microbiological examination of non-sterile products - preparations for peroral administration | 5 530 CZK |
| 35c | Microbiological examination of non-sterile products - preparations containing raw materials of natural origin for which antimicrobial pretreatment is not feasible | 6 960 CZK |
| 35d | Microbiological examination of non-sterile products - premixes for medicated feed for veterinary use with excipients for which antimicrobial pretreatment is not feasible | 6 820 CZK |
| 35e | Microbiological examination of non-sterile products for vaginal administration | 5 670 CZK |
| 36 | Microbiological assay of antibiotics by diffusion plate method | 4 580 CZK |
| 37 | Determination of the number of germs in live bacterial vaccines | 3 260 CZK |
| 38 | Determination of the number of probiotic strains | 3 210 CZK |
| 39 | Bacterial strain identification | 1 770 CZK |
| 40 | Exclusion of bacterial and fungal contamination | 4 190 CZK |
| 41a | Test for mycoplasmas - culture method | 8 310 CZK |
| 41b | Test for mycoplasmas - PCR | 6 520 CZK |
| 42 | Test for bacterial endotoxins | 4 000 CZK |
| 43 | Determination of the potency of inactivated rabies vaccine for veterinary use by NIH test | 56 640 CZK |
| 44 | Determination of the potency of inactivated vaccine against equine influenza in guinea pigs by hemagglutination inhibition test (HIT) | 23 010 CZK |
| 45 | Determination of the potency of inactivated erysipelas vaccine in mice by ELISA method | 15 360 CZK |
| 46 | Determination of virus titer by microtitration method on cell cultures in live virus vaccines | 14 900 CZK |
| 47 | Determination of the potency of inactivated rabies vaccine for veterinary use by serological method with immunofluorescence detection | 26 740 CZK |
| 48 | Determination of Newcastle disease virus titer in chicken embryos | 13 920 CZK |
| 49 | Determination of the number of hyphae in vaccine | 1 980 CZK |
| 50 | Determination of infectious bursal disease virus (IBDV) titer | 13 220 CZK |
| 51 | Determination of rabies virus titer by microtitration method | 14 900 CZK |
| 52 | Testing for the presence of a viral agent by PCR method | 5 920 CZK |
| 53 | Testing for the presence of a viral agent by qPCR method | 5 920 CZK |
| 54 | Determination of the potency of avian or bovine tuberculin PPD in guinea pigs | 39 150 CZK |
| 55 | Sensitization test - avian or bovine tuberculin PPD | 24 070 CZK |
| 56 | Determination of glycoprotein in inactivated rabies vaccine for veterinary use by ELISA method | 12 840 CZK |
| 57 | Determination of infectious bovine rhinotracheitis (IBR) virus titer by microtitration method | 12 790 CZK |
| 58 | Determination of the potency of inactivated vaccine against infectious bovine rhinotracheitis (IBR) in guinea pigs by ELISA method, gE antibodies detection | 26 480 CZK |

| TESTING OF BATCHES OF IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS | | |
|---|---|---|
| OC - 01 | Control of inactivated erysipelas vaccine (appearance, potency - ELISA) | 15 950 CZK |
| OC - 02 | Control of live erysipelas vaccine (appearance, germ count, purity, strain typing) | 9 810 CZK |
| OC - 03 | Control of peroral live rabies vaccine for veterinary use (appearance, virus titer) | 15 490 CZK |
| OC - 04 | Control of inactivated rabies vaccine for veterinary use (appearance, potency - NIH test) | 57 230 CZK |
| OC - 05 | Control of inactivated vaccine against equine influenza (appearance, potency) | 23 600 CZK |
| OC - 06 | Control of inactivated rabies vaccine for veterinary use (appearance, potency - serological method) | 27 330 CZK |
| OC - 07 | Control of diagnostic product containing avian or bovine tuberculin PPD (appearance, sensitization, potency) | 63 810 CZK |
| OC - 08 | Control of inactivated rabies vaccine for veterinary use (appearance, determination of glycoprotein) | 13 430 CZK |
| OC - 09 | Control of live vaccine against infectious bovine rhinotracheitis (IBR) (appearance, virus titer) | 13 380 CZK |
| OC - 10 | Control of inactivated vaccine against infectious bovine rhinotracheitis (IBR) (appearance, gE antibodies detection) | 27 070 CZK |
| OC - 11 | Control of diagnostic product containing avian or bovine tuberculin PPD - using a shortened testing scheme (appearance, potency) | 39 740 CZK |

# Annex 2: Proof of payment of the administrative fee/Doklad o zaplacení správního poplatku

**Č.j./ *Ref.No.***

**Žadatel** = **Dosavadní držitel rozhodnutí o registraci/veterinární lékař**
**Applicant = Current Marketing Authorisation Holder/Veterinarian**
Název (společnosti nebo jméno právnické osoby) / Name (Company/Legal entity):
Adresa / Address:
Země / Country:
IČO:
DIČ:
ID DS:

**Osoba zmocněná k jednání dosavadním držitelem rozhodnutí o registraci[4)]**
**Person authorised to act on behalf of the current Marketing Authorisation Holder[4)]**
Jméno / Name:
Adresa / Address:
Země / Country:
Telefon / Phone Number:

E-Mail:

ID DS (pro ČR) pro zaslání dokladu:

| **Typ žádosti /*Application/Procedure*** | **CZK** | |
|---|---|---|
| Žádost / *Application* | | |
| - **o vydání osvědčení** výrobci veterinárních přípravků o splnění požadavků SVP/ *for the issuance of a certificate for a manufacturer of non-medicinal veterinary products - compliance with GMP requirements* | **2000,-** | ☐ |
| - **o registraci** veterinárního léčivého přípravku, včetně zvykového rostlinného veterinárního léčivého přípravku nebo homeopatického přípravku / *for marketing authorisation of a veterinary medicinal product, including a traditional herbal veterinary medicinal product or a veterinary homeopathic product.* | **2000,-** | ☐ |
| - **o změnu** rozhodnutí o registraci veterinárního léčivého přípravku, včetně homeopatického přípravku, záznam změny VRNA do databáze Unie/podání změny typu VRA /for *variation to a marketing authorisation for a veterinary medicinal product, including homeopathic products; recording of a VNRAs in the Union Product Database (UPD) / submission of a VRA.* | **2000,-** | ☐ |
| - **o převod** registrace veterinárního léčivého přípravku, včetně homeopatického přípravku / *for transfer of the marketing authorisation for a veterinary medicinal product, including a homeopathic product.* | **2000,-** | ☐ |
| - o povolení souběžného dovozu = paralelního obchodu veterinárního léčivého přípravku, včetně homeopatického přípravku / *for authorisation of parallel trade of a veterinary medicinal product, including a homeopathic product.* | **2000,-** | ☐ |
| - **O zrušení** rozhodnutí o registraci veterinárního léčivého přípravku, včetně homeopatického přípravku / *for withdrawal of the marketing authorisation for a veterinary medicinal product, including a homeopathic product.* | **1000,-** | ☐ |
| - **o vydání rozhodnutí v případech pochybností**, zda jde o veterinární léčivý přípravek nebo o léčivou látku nebo o léčivý přípravek podléhající registraci nebo o jiný výrobek, popřípadě zda jde o veterinární homeopatický přípravek/ *for the issuance of a decision in cases of doubt as to whether a product is a veterinary medicinal product, a medicinal substance, a product subject to authorisation, or another type of product, including whether it is a veterinary homeopathic product.* | **2000,-** | ☐ |
| - **o schválení povolení** pro uvádění do oběhu a použití veterinárního léčivého přípravku, který není registrovaný v Evropské unii nebo ve třetí zemi (**veterinární speciální léčebný program**) / *for authorisation of the marketing and use of a veterinary medicinal product not authorised in the EU or a third country (Veterinary Special Treatment Programme)* | **2000,-** | ☐ |
| - **o schválení klinického hodnocení nebo ověřovacího klinického hodnocení** veterinárního léčivého přípravku/ - *for authorisation of a clinical trial or a confirmatory clinical trial of a veterinary medicinal product* | **2000,-** | ☐ |

| | | |
|---|---|---|
| Žádost / *Application* | | |
| - o povolení či změnu povolení k výrobě veterinárních léčivých přípravků/ *for a manufacturing authorisation or a variation thereof for veterinary medicinal products and veterinary autogenous vaccines.* | **2000,-** | ☐ |
| - o povolení nebo změny povolení výroby veterinárních transfuzních přípravků nebo biologických veterinárních léčivých přípravků/ *for a manufacturing authorisation or a variation thereof for the manufacture of veterinary transfusion products or biological veterinary medicinal products.* | **2000,-** | ☐ |
| - o povolení nebo změnu povolení výroby v zařízení transfúzní služby/ *for a manufacturing authorisation or a variation thereof for manufacturing in a transfusion service facility.* | **2000,-** | ☐ |
| - o povolení či změnu k výrobě veterinárních léčivých přípravků - veterinárních autogenních vakcín / for *granting or variation to a manufacturing authorisation for veterinary autogenous vaccines* | **2000,-** | ☐ |
| - o povolení či změnu povolení k činnosti kontrolní laboratoře / *for an authorisation or a variation thereof for the activities of a control laboratory.* | **2000,-** | ☐ |
| Žádost / *Application* | | |
| - o povolení či změnu povolení k distribuci léčivých přípravků / *for a wholesale distribution authorisation or a variation thereof for veterinary medicinal products.* | **2000,-** | ☐ |
| - o rozšíření povolení k distribuci / *for an extension of a wholesale distribution authorisation.* | **2000,-** | ☐ |
| Vydání stejnopisu, opisu, kopie, fotokopie nebo výpisu/ *Issuance of duplicate, transcript, copy, photocopy or extract* | | |

**Datum**
***Date***

**Podpis žadatele, popř. jím zmocněné osoby**
***Signature of the applicant, or their authorised representative***
Jméno, příjmení / *Name and Surname:*
Adresa / *Address*:

Číslo jednací žádosti: Přijata na ÚSKVBL dne: Jméno/podpis:

POTVRZENÍ PŘÍJMU PLATBY
Platba bankovním převodem - číslo výpisu: Datum výpisu:

…… ……..

**Datum** **Za Odbor ekonomiky a financování ÚSKVBL**

# Annex 3: Confirmation of Payment of Reimbursement of Costs for Expert Tasks Performed within the Scope of ÚSKVBL / Annual Maintenance Fee

## (TAX DOCUMENT)

| |
|---|
| **Applicant / Marketing Authorisation Holder -** Name, Address<br><br>**Contact Address** - Name, Address, Phone, E-mail (complete only if different from the address of the authorised representative)<br><br>Data Box ID (for CZ) |
| **Authorised Representative -** Name, Address<br><br>**Contact Address -** Company/Name, Address, Phone, E-mail,<br><br>and Data Box ID (for delivery of the document) |
| **Name of the veterinary medicinal product,** pharmaceutical form, strength (not to be completed for applications regarding inspection, laboratory testing and clinical trials) |

| **Application for (complete the data according to this guideline)** | |
|---|---|
| Activity code | Activity |
| | |

**Variable symbol (mark the option applicable to your payment with a cross and fill in the corresponding variable symbol):**

☐ **activities related to marketing authorisation**:

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |

☐ **annual maintenance fee:**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |

☐ **activities related to inspection, laboratory testing, determination of residues, clinical trials, EU-level activities, or general tasks:**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |

| Paid by bank transfer | | |
|---|---|---|
| Amount paid in CZK: | Payment order submitted on: | |
| **Person remitting the payment** (mark the person remitting the payment to ÚSKVBL with a cross) **- Payer:** | | |
| ☐ Applicant / Marketing Authorisation Holder | ☐ Authorised Representative | |
| **Person to whom the confirmation of payment of reimbursement of costs for expert tasks / annual maintenance fee confirmed by ÚSKVBL shall be sent** (mark the person with a cross) | | |
| ☐ Applicant / Marketing Authorisation Holder | ☐ Authorised Representative | |
| Name of the bank executing the transfer: | Payer's bank account number: | Constant symbol: |

| To be completed by the ÚSKVBL Registry: | | |
|---|---|---|
| Reference number (Application ID): | Received by ÚSKVBL on: | Name, signature: |
| **CONFIRMATION OF RECEIPT OF PAYMENT** | | |
| Payment by bank transfer - Bank statement number: | | Bank statement date: |
| ……. | | ……. |
| **Date** | | **On behalf of the Economy and Finance Department of ÚSKVBL** |

## Annex 4: Request for Refund of Administrative Fee

Ústav pro státní kontrolu veterinárních biopreparátů a léčiv
Hudcova 232/56a
621 00 Brno
Czech Republic

# Request for Refund of Administrative Fee

| | | |
|---|---|---|
| Ref.No./File No. of the application: | | |
| Type of application: | | |
| Product name (in case of applications related to marketing authorisations): | | |
| Specification of the application content: | | |
| Name of the applicant: | | |
| Address of the applicant: | Street, House No. / P.O. Box: | City, Postcode, Country: |
| Contact person | | |
| Address of the contact person: | | Phone: |
| Amount paid in CZK: | | Date of payment: |
| Variable symbol of the application: | | Refund in currency: |
| Name of the applicant's financial institution: | | Address: |
| Account number / Bank code: | | IBAN (International Bank Account Number): |
| SWIFT address (if known): | | National clearing code - if known: |
| Reasoning (Justification): | | |
| Reference to sources where the claim can be verified: | | |

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Date Name and signature of the applicant
stamp

***Do not complete – for ÚSKVBL internal use only***

The refund of the administrative fee is/is not in accordance with Section 7 of the Act on Administrative Fees:

- the requested task was not performed; an administrative fee (AF) not included in the tariff was paid; the AF was paid by a person who is not the taxpayer; or an overpayment of the AF occurred.

Therefore, I agree/disagree with the refund of the amount: ..... CZK

Date Name and signature of the Head of the relevant Department

A decision was issued under File No. ..... on ....., by which it was decided to:
a) refund the administrative fee in full
b) refund a portion of the administrative fee in the amount of .....
c) reject the request for refund of the administrative fee

Date Name and signature of the Head of the Economy and Finance Department

## Annex 5: Request for Refund of Reimbursement of Costs

Ústav pro státní kontrolu veterinárních biopreparátů a léčiv
Hudcova 232/56a
621 00 Brno
Czech Republic

# Request for Refund of Reimbursement of Costs

| | | |
|---|---|---|
| Ref. No. / File No. of the application: | | |
| Expert task: | | |
| Activity code: | | |
| Název přípravku v případě žádostí ve věci registrací: | | |
| Product name (in case of applications related to marketing authorisations): | | |
| Name of the applicant: | | |
| Address of the applicant: | street, house no./P.O. box | city, postcode, country: |
| Contact person: | | |
| Address of the contact person: | | Phone: |
| Amount paid in CZK: | | Date of payment: |
| Variable symbol of the application: | | Refund in currency: |
| Name of the applicant's financial institution: | | Address: |
| Account number/bank code: | | IBAN: |
| SWIFT address - if known: | | National clearing code - if known: |
| Reasoning (Justification): | | |
| Reference to sources where the claim can be verified: | | |

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Date

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Name and signature of the applicant
stamp

***Do not complete - for ÚSKVBL internal use only***
Verification of the facts stated in the reasoning:
Opinion of the department performing the expert task:
Decision - Head of Department:

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Date

---
Name and signature - Head of Department

---
Date

---
Name and signature - Head of the Economy Department