**ÚSKVBL/UST-1/2025**

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

**Administrative fees and reimbursements of costs of expert activities carried
out in the competency of the Institute for State Control of Veterinary Biologicals and Medicines**

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 **Replaces: ÚSKVBL/UST - 4/2008/Rev. 6 and Clarifying information to instruction ÚSKVBL/UST - 4/2008/Rev. 5**

Brno, 10 January 2025 MVDr. Jiří Bureš,

 Director ÚSKVBL

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# 1. Introduction

This guidance provides information regarding administrative fees and reimbursement of costs of expert activities carried out in the competency of Institute for State Control of Veterinary Biologicals and Medicines (ÚSKVBL).

The reason for issuing this guidance and replacing the previously valid one was the need to update all information and guidance following legislative changes that were related to the start of the application of Regulation (EU) 2019/6 on veterinary medicinal products, the amendment to the Act on Pharmaceuticals, as amended No. 378/2007, Coll., the amendment to the Act No. 634/2004 Coll., on Administrative Fees, and to respond to Act No. 349/2023 Coll., which amends certain acts as of January 1, 2024, in connection with the consolidation of public budgets, including the Tax Code and the Act on Administrative Fees, in the sense of abolishing stamp duties, i.e., the possibility of paying administrative fees by means of revenue stamps.

Since 2022, the guidance has regulated payments for activities performed by the Institute for State Control
of Veterinary Biologicals and Medicines under the Act on Pharmaceuticals, as amended in connection with the applicability of Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products (hereinafter referred to as the "VMP Regulation") (direct applicability from January 28, 2022).

In addition, at the end of the same year, changes were made to the tariff of fees in Annex to the Act
on Administrative Fees, Part VI - Item 97, from which the ÚSKVBL's obligation to collect administrative fees
for newly introduced items arises.

The VMP Regulation changes some existing rules for the marketing authorisation of veterinary medicinal products and their post-marketing authorisation procedures in the EU. This Regulation is directly applicable, however,
in many respects it requires Member States to adopt implementing or adaptation rules, and in many respects
it allows Member States to set their own regulatory conditions, which is also the case for setting administrative fees and reimbursements of costs of expert activities in the field of veterinary medicinal product regulation.

The national adaptation regulation is the Act on Medicinal Products, whose adaptation amendment (Act No. 314/2022 Coll., of October 12, 2022) came into force on December 1, 2022, and further amendments to the relevant implementing legal regulations (decrees) will be prepared. This amendment also affected the scope
of administrative fees (as mentioned above), as listed in the Act on Administrative Fees.

The system of administrative fees and reimbursement of costs of expert activities carried out in the competency
of USKVBL must be addressed in this transitional period using the currently valid legislation. Payments for expert activities, which, even under the new conditions, retain the existing scope and regulatory procedures in the main aspects, have been increased in justified cases (reimbursements for laboratory tests of medicinal products and excipients) in view of the increased financial demands of performing these acts.

Adjustments reflecting, for example, inflation or digitalization will be proposed as part of the preparation of the amendment of implementing legislation. This is also reflected in the fact that, for example, payments in connection with the renewal of the marketing authorisation of veterinary medicinal products within the meaning of the previous wording of the Act on Medicinal Products, or Directive 2001/82/EC of the European Parliament and of the Council, will no longer be used.

For the administration of individual professional acts, we have made some technical adjustments in the guidance - for example, the adjustment of the terminology used, the follow-up adjustment of codes for identifying the purpose of payments, or the adjustment of the relevant forms.

In addition to these administrative adjustments, it was necessary to introduce some new acts in response to the new conditions, especially in the area of variations to the marketing authorisation of veterinary medicinal products, which is an area that is undergoing fundamental substantive changes. This concerns in particular the definition
of new marketing authorisation variations for which, within the framework of their approval, no detailed expert
assessment is expected and where the administrative burden associated with the identification of these variations, their assessment and approval is de facto entirely transferred to the regulatory authorities, including the costs
associated with the digitalization of the entire process of administration of these variations (work with the EU database for veterinary medicinal products and the exchange of information between this database and the national database).

The VMP Regulation thus introduces substantial changes in the rules laid down for variations to the marketing authorisation of veterinary medicinal products and changes the way of dividing the types of variations and their classification. The classification of variations according to Commission Regulation (EC) No 1234/2008 (and the guidelines for the various categories of variations, for the implementation of the procedures laid down in Chapters II, IIa, III and IV of Commission Regulation (EC) No 1234/2008) is thus no longer used and, pursuant to Articles 61 and 62 of the VMP Regulation, is replaced by two types of variations, namely those which do not require assessment (VNRA, classification codes begin with the letters A, B, C or D) and those which need to be assessed (classification codes begin with the letters E, F, G, H or I). More on the division of variations can be found in the guideline - ÚSKVBL/REG-1/2022 Information on the new rules for variations to the marketing authorisation of veterinary medicinal products in connection with Regulation (EU) 2019/6, which is available at [http://www.uskvbl.cz/cs/
registrace-a-schvalovani/registrace-vlp/obecne-pokyny-a-informace/obecne-pokyny](http://www.uskvbl.cz/cs/registrace-a-schvalovani/registrace-vlp/obecne-pokyny-a-informace/obecne-pokyny). This also involves changes concerning the reimbursement of expenses in connection with variations to the marketing authorisation
of veterinary medicinal products.

In addition to the area of variations to the marketing authorisation of veterinary medicinal products, it was necessary to extend the existing scope of acts to include other acts performed by the ÚSKVBL arising from the above-described legal amendments (reimbursement of expenses in the field of residue determination, in the field of production authorization for transfusion products, biological veterinary medicinal products, radionuclide generators, in the field of authorisation of importers and distributors of medicinal substances and in the field
of clinical trials).

For the sake of better clarity and to prevent incorrect payments that currently occur, the ÚSKVBL is abolishing two documents, the hitherto valid ÚSKVBL/UST - 4/2008/Rev. 6 guidance and the Clarifying Information thereto, and is issuing this new guidance, which combines all current information in the previously published and above-mentioned documents. The guidance on expert activities also reflects the new terminology and the adjustment
of codes for payment identification.

# 2. Objectives and Scope

The objective of this guidance is to provide regulated entities with detailed and clear rules for the payment
of individual types of payments that are required in accordance with the Act on Medicinal Products and related legislation.

Thus, the guidance includes 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 Medicinal Products are subject to administrative fees. The rules for the payment of administrative fees are governed by Act No. 634/2004 Coll. The amount of administrative fees is set out in the annex to this Act (in the "tariff of fees") and, for clarity, the fee-related acts concerning administrative proceedings conducted by the ÚSKVBL, which have been amended since 1 December 2022, are included in this guidance.

* reimbursement of costs of expert activities upon request and for other expert activities specified by the Act on Medicinal Products, which fall within the competence of the ÚSKVBL,

In accordance with Section 112 of the Act on Pharmaceuticals, as amended, the ÚSKVBL charges
a reimbursement of costs for the performance of expert activities upon request and for other expert activities
specified by this Act. The list of activities that are subject to reimbursement of costs, the amount
of reimbursement of costs and the rules for reducing or waiving the reimbursement of costs are regulated by a decree and this guidance, which takes into account the VMP Regulation. The definition of experts activities that are performed by the ÚSKVBL and the amount of reimbursement of costs for their performance are given in Annex 1 to this guidance.

* reimbursement of costs for ÚSKVBL activities related to the duration of the marketing authorisation
of medicinal products (annual maintenance fee).

The marketing authorisation holder, in accordance with Section 112(2) of the Act on Pharmaceuticals,
as amended, also pays reimbursements of costs for ÚSKVBL activities related to the duration of the marketing authorisation of veterinary medicinal products in the form of annual maintenance fees, in such a way that by the end of the calendar year it is obliged to pay the annual maintenance fee for the following calendar year. The amount of the maintenance fee is given in Annex 1 to this guidance.

# 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, as amendedand on Amendments to Some Related Acts (Act
on Pharmaceuticals), as amended.

Decree No. 427/2008 Coll., on Determining the Amount of Reimbursement of Costs of Expert activitiesperformed within the Competence of the State Institute for Drug Control and the Institute for State Control of Veterinary Biologicals and Medicines, as amended. 1

Commission Implementing Regulation (EU) 2021/17 establishing a list of variations not requiring assessment
in accordance with regulation (EU) 2019/6

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

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

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

# ****4. Rules for Administrative Fee Payments (Act No. 634/2004 Coll.)****

**4.1 Procedure for Administrative Fee Payments**

The obligation to pay an administrative fee arises upon acceptance of applications or certain acts (considering the need to update the Act on Administrative Fees, we only include items that fall within the scope of ÚSKVBL):

|  |  |  |
| --- | --- | --- |
| **Application/Act** | **CZK** | **Note** |
| Item 69 |  |  |
| Application |  |  |
| **-** by a manufacturer of veterinary preparations for the issuance of a certificate of compliance with GMP requirements | **2000,-** |  |
| Item 97 |
| Application |  |  |
| - for marketing authorisation of a veterinary medicinal product, including a traditional herbal veterinary medicinal product or veterinary homeopathic product | **2000,-** |  |
| - for variation to the marketing authorization, including a homeopathic product | **2000,-** |  |
| - for transfer of the marketing authorization for a veterinary medicinal product, including a homeopathic product | **2000,-** |  |
| - for authorization of parallel import of a veterinary medicinal product, including a homeopathic product | **2000,-** |  |
| - for withdrawalof the marketing authorization for a veterinary medicinal product, including a homeopathic product | **1000,-** |  |
| * for issuance of a decision in cases of doubts as to whether it is a veterinary medicinal product or a medicinal substance or a medicinal product subject to registration or another product, or whether it is a veterinary homeopathic product
 | **2000,-** |  |
| * for approval of authorization for placing on the market and use of a veterinary medicinal product that is not registered in the European Union or in a third country (veterinary special treatment program)
 | **2000,-** |  |
| * for approval of a clinical trial or confirmatory clinical trial of a veterinary medicinal product
 | **2000,-** |  |
| Item 98 |
| Application |  |  |
| - for manufacturing authorization or change to the authorization for the manufacture of veterinary medicinal products and veterinary autogenous vaccines | **2000,-** |  |
| - for manufacturing authorization or change to the authorization for the manufacture of veterinary transfusion products or biological veterinary medicinal products | **2000,-** |  |
| - for manufacturing authorization or change to the authorization for the activities of a control laboratory | **2000,-** |  |
| - for manufacturing authorization or change to the authorization for manufacture in a transfusion service facility | **2000,-** |  |
| Item 99 |
| Application |  |  |
| - for wholesale distribution authorisation or change to the authorization for the wholesale distribution of veterinary medicinal products | **2000,-** |  |
| - for extension of the wholesale distribution authorization | **2000,-** |  |
| Item 3 |
| Issuance of a duplicate, copy, transcript, photocopy, or extract from official files, registers, records, evidence, documents, or other written and visual material, or notification of a negative finding. | 50 CZK | for each started page |
| 30 CZK | for the first pagefor each subsequent started page, if produced on a photocopier or computer printer | |
|  and 10 CZK |

**Administrative fees are paid by transfer to an account held at the Czech National Bank.**

**A bank statement from the applicant confirming the payment of the relevant administrative fee is attached
to the application.**

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

(Note: Act No. 349/2023 Coll., which amends certain laws in connection with the consolidation of public budgets, also amends the Tax Code and the Act on Administrative Fees as of January 1, 2024, in terms of the abolition
of revenue stamps, effective from January 1, 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 someone held revenue stamps issued before this date, they could use them no later than December 31, 2024).

**ÚSKVBL data for bank transfer of the administrative fee:**

|  |  |
| --- | --- |
| Bank name | Česká národní banka (ČNB) - pobočka Brno |
| Bank address | Rooseveltova 18631 32, BrnoCzech Republic |
| Account number | 19-31229641 |
| Bank code | 0710 |
| IBAN code | CZ98 0710 0000 1900 3122 9641 |
| BIC (originally Swift code) | CNBACZPP |
| Constant symbol | 1148 |
| Variable symbol | Generated by the below specified procedure |
| 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/actions listed in Item 97 (see table point 4.1),
* Applications/actions listed in Item 69, 98 or 99 or in Item 3 (see table point 4.1).

**A.** In the case of applications/actions listed in **ITEM 97**, the applicant obtains the variable symbol as follows:

* The variable symbol is **ten digits long**,
* **The first position** of the variable symbol is the number
* **5** (for an action in the field of clinical trials) or
* **1** (for all other actions in Item 97 related to the field of marketing authorization),
* **The next two** positions of the variable symbol represent the Item number from the Act on Administrative Fees, namely
* **97** (see table point 4.1),
* **The next four positions**
* represent the middle part of the medicinal product marketing authorization number,
* in the case of products that have not yet been authorized (for example, a marketing authorizationapplication) or in the case of clinical trials or decisions in cases of doubt, **four zeros** are entered;
* for a special treatment program, the veterinarian enters the registered **four-digit number under which it is authorizedwith the KVL** (if the KVL number is not available,four zeros are entered).

The number is always entered as four digits, so in the case of a product authorized under marketing authorization number 96/047/01-C, the symbol 0047 is entered (see example below). If it is a grouping
of several marketing authorizations of the same holder, the middle part of the marketing authorization number of the medicinal product listed first in the application is entered,

* **The next one position** represents the serial number of the application submitted - usually 1 is entered.
If the applicant pays multiple applications related to the same action or even the same medicinal product
in one month, these payments are marked with an increasing number (for example, the first payment for
a change in the marketing authorization of product A in May means entering the symbol 1, another payment for a change in the marketing authorization of product A in May means marking the symbol 2, etc. In the case of more than 9 changes in the case of payment for the same action, in one calendar month for the same product, payment must be made in the following month). In the example below, 2 is given, which means that the applicant is paying the second administrative fee for a change in the decision in May - 05 - for a product authorized under marketing authorization number - 0047,
* **The last two positions** of the variable symbol indicate the month in which the payment is made.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Area – Marketing authorization Registration** | **Action Code** | **Reg. Number - Middle Section/MA.Number at KVL** | **Payment Sequence Number** | **Month of Payment** |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1** | **0** | **9** | **0** | **0** | **4** | **7** | **2** | **0** | **5** |

or

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Area - Clinical Evaluation** | **Action code** | **Clinical Evaluation** | **Payment Sequence Number** | **Month of payment** |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1** | **0** | **9** | **0** | **0** | **4** | **7** | **2** | **0** | **5** |

**Always include the name of the preparation or product to which the payment relates in the recipient's message, even if it is an already authorized product for which you can enter the middle marketing authorization number!!!!!**

(If the administrative fee payment relates to one application for multiple marketing authorization numbers, enter the name of the product that is listed first in the application.)

**B.** **In the case of applications relating to actions listed in ITEM 69, 98 or 99 or 3**, the applicant obtains the variable symbol as follows:

* The variable symbol is **nine digits long**.
* **The first position** of the variable symbol is the number
* **2** for the inspection area (manufacturing, distribution, control laboratories) or
* **9** for the general area (administrative actions)
* **The next two positions** of the variable symbol represent the Item number from the Act on Administrative Fees, namely
* **69 or**
* **98 or**
* **99 or**
* **03 (item listed with a zero so that the number is always two digits)**
* **The next four positions represent the day (01 - 31) and month (01 - 12) of payment** (for example, for
a payment made on April 3, the symbol 0304 is entered),
* **The next two positions represent the year of payment** (for example, for the year 2024, the symbol 24
is entered).

In the example below, the variable symbol for an administrative fee associated with an application for authorization or amendment of authorization for the distribution of veterinary medicinal products, paid on October 4, 2024,
is given:

|  |  |  |  |
| --- | --- | --- | --- |
| **Area – INS-2,** **GEN- 9** | **Action code** | **Day + month of the payment** | **Year of the payment** |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **2** | **9** | **9** | **0** | **4** | **1** | **0** | **2** | **4** |

**4.3. Refund of Administrative Fees**

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

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

We recommend using the "Application for Refund of Administrative Fee" form (Annex 4) for the request.

# ****5.**** Rules for Payment of Reimbursement of costs of expert activities

**5.1. General Rules**

For expert activities performed within its scope of authority, ÚSKVBL collects reimbursements of costs according to Section 112 of the Act on Pharmaceuticals, as amended. **The reimbursement of costs is paid before the application is submitted by bank transfer to an account held at the Czech National Bank in the amount specified in Annex 1.**

**Proof of payment (bank statement) is attached to the relevant application.**

**ÚSKVBL data for bank transfer of reimbursement of costs of expert activities**

|  |  |
| --- | --- |
| Bank name | Česká národní banka (ČNB) - pobočka Brno |
| Bank address | Rooseveltova 18631 32, BrnoCzech Republic |
| Account number | 35-31229641 |
| Bank code | 0710 |
| IBAN code | CZ 76 0710 0000 3500 3122 9641 |
| BIC (originally Swift code) | CNBACZPP |
| Constant symbol | 1148 |
| Variable symbol | Generated by the below specified procedure |
| Payment title | 355 - Research and development |

In order to easily and unambiguously assign individual payments to individual applications, a variable symbol generated for individual application categories using the procedure described below is used to prevent
the repetition of the variable symbol. We also recommend including the name of the preparation (if not available, the requested action) to which the payment relates in the bank payment order note. If it is a grouped application for multiple marketing authorization numbers, the name of the preparation that is listed first in the application
is entered.

Cases where payment is not required before submitting the application and where the generated variable symbol is already sent to the applicant by ÚSKVBL are listed later in points 5.1.3 and 5.2.

The Act on Pharmaceuticals allows reimbursements of coststo be collected in advance. Therefore, a bank statement from the applicant confirming the payment is attached to the relevant application.

A pre-filled document "Confirmation of Payment of Reimbursement of costs of expert activities Performed within the Scope of ÚSKVBL" is always attached to all applications of expert activities that are subject to reimbursement of costs. This document is included in Annex 3 of this instruction.

After identifying the payment on the above-mentioned ÚSKVBL account, a confirmed copy of the document submitted with the application will be sent back to the applicant as a tax document.

**If the applicant does not submit the required documents, the application will be assessed as incomplete.**

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

We would like to remind applicants that when paying reimbursements of costs by bank transfer, it is necessary to take into account the bank transfer fees in order to pay the full amount so as to avoid underpayments. The payment must be made in such a way that the bank fees are paid by the applicant and the full amount corresponding to the specified amount of the administrative fee or reimbursement of costs for the given action, which is stated on the
document "Confirmation of Payment of Reimbursement of costs of expert activities performed within the Scope
of ÚSKVBL" depending on the type of application, is transferred to the ÚSKVBL account. The symbol "OUR" must be included in the payment order for this purpose.

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

Each payment for the relevant application must be made separately with one item of the payment order so that unambiguous identification of the payment is possible, and therefore it is not possible to pay multiple reimbursements of costs (for several applications submitted) with one joint amount. The reason for separating individual payments from one applicant is the need to work with each application completely separately so that any payment problems with one application do not block other applications.

Also, unused or mistakenly sent payments or overpayments from one application cannot be transferred to another application. In such a case, the applicant requests a refund of the reimbursement of costs using the form - Annex 5, and these payments will be refunded to them.

In the case of grouping changes to one or more marketing authorizations of the same holder into one application, the applicant pays one lump sum for all changes requested in the application.

The amounts of reimbursement of costs for the mutual recognition procedure and the decentralized procedure are the same if the Czech Republic is the competent/concerned state.

**We remind applicants to comply with the transfer of payments of both administrative fees and reimbursements of costs to the correct accounts and in the correct amounts.**

**5.1.1. Reimbursement of costsof expert activities for Applications for Change of marketing authorisation with Worksharing**

In the case of applications for changes of marketing authorisation requiring evaluation (VRA - classification codes E, F, G, H), where the worksharing principle is applied and the application includes one or more different VRA changes, the reimbursement of costsof expert activities is paid as follows:

* For each change included, the amount required for the given type of change is paid, taking into account the timetable (R/S/E), regardless of the fact that the standard timetable is most often used for applications with the worksharing principle.

The amounts of reimbursement of costs for national marketing authorizations that are included in international procedures (MRP) within the framework of worksharing are governed by the tariff for international procedures, distinguishing whether the Czech Republic acts as a reference authority or a competent (concerned) member state.

**5.1.2. Changes of marketing authorizationsRegistrations Related to Detailed Description of the Pharmacovigilance System**

In the case of changes of marketing authorizations related to the detailed description of the pharmacovigilance system or the risk management system that the marketing authorization holder has implemented,
the reimbursement of costs is paid in the amount according to the type of change specified by Commission Implementing Regulation (2021/17) or the CMDv coordination group guideline to specify the classification
of changes requiring assessment.

Exceptions are changes related to pharmacovigilance that are introduced by marketing authorization holders into the European database of medicinal products (hereinafter "UPD") due to the fulfillment of this database and are not a factual change of the pharmacovigilance system (e.g., change C.1 and C.6 - for the purpose of entering data of the qualified person QPPV and PSMF summary into UPD, but only if it is not a change in the PSMF (e.g., after transfer of marketing authorization) or data such as the name or address of QPPV).

**5.1.3. Amount of Reimbursement of costs of expert activities That Are Not Listed in Annex 2 of Decree No. 427/2008 Coll., or Do Not Specify the Required Method**

The amount of reimbursement of costs of expert activities that are not listed in Annex 2 of Decree No. 427/2008 Coll., or do not specify the required method, is determined according to the formula given in Annex 3 of this decree. Here is the calculation formula according to which the fee amount is determined.

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

**Calculation Formula**

Amount of Reimbursement of costs (in CZK) = x \* b

where:

x = number of working hours (each started hour)

b = costs per 1 hour of work, which include wage costs, material costs, activities and domestic travel costs

(Note: the amount of costs ("b") is currently set at CZK 490, but 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 amount).

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

**5.2 Rules for Reimbursement of costs of another expert activities - Additional Payments for the pending Marketing Authorization Procedure**

According to the tariff of reimbursements of costs (see Annex 1 of this instruction), additional activities are charged, which are performed only in cases where applications are submitted that do not contain data and documentation (marketing authorization documentation) that meet the applicable requirements.

These are applications for new marketing authorization and changes to the marketing authorization (type S and E) carried out by the national procedure.

The additional payment is required only once during one procedure, even if the application is supplemented several times in some cases. An exception is those situations where the required supplementation is particularly extensive and therefore requires further thorough evaluation. In these exceptional cases, ÚSKVBL may require repeated payment of the additional payment.

The notice of additional payment, together with the pre-generated variable symbol for this payment, is in most cases part of the first request to supplement the application in terms of the content of the registration documentation (not requests related to the validation of the application). Documents proving the additional payment are sent together with the supplementary documentation. In the cover letter to the shipment, please include the file number under which the application is processed.

**5.3. Obtaining a Variable Symbol for Reimbursement of costs payment:**

The variable symbol differs in the case of

* applications relating to actions in the field of marketing authorisation of veterinary medicinal products (see Annex 1, chapter REGISTRATION),
* applications relating to inspection, laboratory activities, clinical trials, or general actions (see Annex 1, chapter **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 relating to activities in the field of Marketing authorization of veterinary medicinal products, the applicant obtains the payment variable symbol as follows:

* The variable symbol is **ten digits long**,
* **The first position** of the variable symbol is **1** (actions in the field of registration),
* **The next two positions** of the variable symbol represent the action code (see Annex 1 - code for VarS purposes) - e.g., 14 - application for transfer of registration;

If the same basic action code has multiple variants (e.g., 17a, 17b, 17c), only the basic code is given in the position of the variable symbol (e.g., 17); if it is a grouping of changes in one application, the code for the main - "highest" change from which other changes result is given,

**the next four positions** represent the middle part of the medicinal product marketing authorization number, in the case of products that have not yet been authorized (for example, a marketing authorization application), **four zeros** are entered; **the number is always entered as four digits**, so in the case of a product authorized under marketing authorization number 96/047/01-C, the symbol 0047 is entered (see example below). If it is a grouping of several marketing authorizations of the same holder, the middle part of the marketing authorization number of the medicinal product listed first in the application is entered,

* **the next one position** represents the serial number of the application submitted - usually 1 is entered. If the applicant pays multiple applications related to the same action and the same medicinal product in one month, these payments are marked with an increasing number (for example, the first payment for a change in the marketing authorization of product A in May means entering the symbol 1, another payment for a change in the marketing authorization of product A in May means marking the symbol 2, etc. In the case of more than 9 changes in the case of payment for the same action, in one calendar month for the same product, payment must be made in the following month (in the example below, 2 is given, which means that the applicant is paying the second application for a change - 10 - in May - 05 - for a product authorized under marketing authorization number - 0047,
* **the last two positions of the variable symbol indicate the month in which the payment is made.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **MA area** | **Action code** | **MA number - middle part** | **Serial payment number** | **Month of payment** |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1** | **1** | **0** | **0** | **0** | **4** | **7** | **2** | **0** | **5** |

**B. In the case of applications relating to actions 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 ACTIONS**, the applicant obtains the payment variable symbol as follows:

* The variable symbol is **nine digits long**,
* **The first position** of the variable symbol in the case of actions in the field of
* INSPECTION is 2,
* LABORATORY ANALYSIS, BATCH RELEASE is 3,
* DETERMINATION OF RESIDUES OF PHARMACOLOGICALLY ACTIVE SUBSTANCES IN BIOLOGICAL MATERIALS is 4,
* CLINICAL TRIALS is 5,
* ACTIVITIES WITHIN THE EUROPEAN UNION is 6 and in the field of
* GENERAL ACTIONS is 7,
* **The next two positions** of the variable symbol represent the action code (see Annex 1 - code for VarS purposes) - e.g., 04 in the field of INSPECTION - Application for authorization for the manufacture
of veterinary medicinal products with inspection at the manufacturing site - for the scope of sterile veterinary medicinal products - one pharmaceutically different dosage 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 is given in the position of the variable symbol (e.g., 29),

* **The next four positions** represent **the day** (01 - 31) and **month** (01 - 12) of payment (for example,
for a payment made on April 3, the symbol 0304 is entered),

* **The next two positions** represent the year of payment (for example, for the year 2024, the symbol 24
is entered).

In the example below, the variable symbol for reimbursement of expenses associated with an application for authorization for the manufacture of veterinary medicinal products with inspection at the manufacturing site - for the scope of sterile veterinary medicinal products - one pharmaceutically different dosage form, or one production unit - line at one manufacturing site (national authorization for a manufacturer in the Czech Republic), made on October 4, 2024, is given:

|  |  |  |  |
| --- | --- | --- | --- |
| **Area - INS-2, LAB-3, REZIDUES-4, KLIN-5, EU-6,** **GEN- 7** | **Action code** | **Day + month of the payment** | **Year of the payment** |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **2** | **0** | **4** | **0** | **4** | **1** | **0** | **2** | **4** |

In the case of applications for GMP inspection in a third country[[1]](#footnote-1)\*, an amount corresponding to the required type
of inspection specified in the tariff (Annex 1) is paid in advance, and an agreement on the reimbursement of travel expenses of the inspector is drawn up with the applicant, consisting of:

* air transport to the location closest to the inspection site in "economy" class in the case of a flight within Europe, and in "business" class in the case of a flight outside Europe,
* coverage of accommodation costs in a standard category hotel for the necessary number of days,
* costs of stay and local transport at the daily rate specified by the relevant currently valid legal regulation. The inspector's arrival at the inspection site is usually expected the day before the start of the inspection, and departure on the last day of the inspection or the following day.

In the case of an application for laboratory analysis, the applicant shall state the control regulation (pharmacopoeial article, registration documentation) according to which the analysis is to be performed, or shall state the individual control methods. The reimbursement, which the applicant calculates according to the individual items listed in the tariff, shall be paid in advance. A breakdown of the individual items shall be submitted with the application. In the case of special control methods requiring the purchase of reference substances or expensive chemicals or kits, where the ÚSKVBL expenses exceed the tariff items, the institute shall inform the applicant immediately after the application is submitted and inform him of the amount of additional costs. The analysis will be performed after the applicant approves these costs.

**5.4 Refund of Reimbursement of Expenses**

ÚSKVBL refunds the reimbursement of expenses according to Section 112(4) of the Act on Pharmaceuticals
on the basis of a signed application sent to ÚSKVBL. The application form is given in Annex 5 of this instruction.

ÚSKVBL refunds the applicant the reimbursement of expenses or part thereof in one of the following cases:

a) if the applicant paid the reimbursement of expenses without being obliged to do so, ÚSKVBL refunds
the reimbursement in full,

b) if the proceedings or the required professional action were not initiated at all, ÚSKVBL refunds
the reimbursement in full,

c) if the applicant paid a higher amount than is specified for the given professional action, ÚSKVBL refunds
the difference between these amounts,

d) if the applicant paid and then ÚSKVBL, at his additional reasoned request, waived the payment, ÚSKVBL refunds the reimbursement in full,

e) if the administrative proceedings are stopped at the applicant's request or the professional action not carried out in the administrative proceedings is terminated at the applicant's request, ÚSKVBL refunds a proportional part of the paid reimbursement of expenses corresponding to the professional actions that were not carried out until the termination of the proceedings; if an evaluation report has already been prepared, all professional actions are considered to have been carried out.

If the amount that ÚSKVBL is obliged to refund is less than CZK 100, ÚSKVBL does not refund the reimbursement
or part thereof.

**5.5. Waiver and Reduction of Reimbursement of Expenses**

The rules for waiving and reducing expenses are governed by Section 4 of Decree No. 427/2008 Coll.,
and the following are cases, especially with regard to the direct application of the VMP regulation (2019/6).

**5.5.1. Waiver of Reimbursement of costs or Part Thereof**

Reimbursement of costs can only be reduced or waived upon request. If, in a given case, one of the legal reasons
is met, the applicant submits a request for reduction or waiver of the reimbursement of costs justified in accordance with the provisions of Section 112 of the Act on Pharmaceuticals, as amended together with the request for expert activity in the form of a cover letter.

ÚSKVBL, upon request, waives the reimbursement of costs or part thereof if it is a transfer of marketing authorization or activities, the performance of which is in the public interest or may have particularly significant consequences for a wider range of people, 1 especially if it concerns veterinary medicinal products intended for use in minor animal species or in minor indications that have been designated in accordance with the Commission and EMA guidelines published in the information medium of the Veterinary Institute.

**5.5.2. Other Options for Reducing Reimbursement of costs**

**Reduction of Reimbursement of costs for VNRA Changes**

For changes not requiring assessment (VNRA - classification codes A, B, C, D), the system of reducing reimbursement of costs remains in place. The following rules apply to the reduction of reimbursement of costs of expert activities:

* one identical change for multiple marketing authorization numbers - the reimbursement of costs is paid in full for the first marketing authorization number, and the applicant may request a 50% reduction of the reimbursement of costs for all remaining marketing authorization numbers,
* a group of identical changes for multiple marketing authorization numbers - the reimbursement of costs
is paid in full for the first marketing authorization number, for all requested changes. The applicant may request a 50% reduction of the reimbursement of costs for all identical changes of the remaining marketing authorization numbers.

This rule may also be applied in exceptional situations (especially due to technical difficulties) in a situation where notifications for an identical change/group of identical changes in UPD are made for each marketing authorization number separately, but only if these submissions are made in quick succession (and can therefore be considered
a so-called technical grouping).

**Reduction of Reimbursement of costs for VRA Changes**

Unlike the principle of paying the amount of reimbursement of costs of expert activities set for individual types
of VRA changes according to the timetable set for each classification code, a fee reduction is applied:

a) for a change marked G.I.18. This is a change of the existing template for SPC/packaging/package leaflet texts
to version 9 (or a newer version). In accordance with Article 152(2) of the VMP regulation, this change should be submitted so that the change is completed and implemented on the packaging and package leaflet by January 29, 2027. The mentioned change has a standard timetable - S. However, ÚSKVBL took into account the volume of work performed for expert activities within the application for this type of change G.I.18 and adjusted the required amount of reimbursement of costs so that it corresponds to the amount of reimbursement of costs for changes with a reduced timetable - R (see also Annex 1).

b) for a change/changes of national marketing authorizations of immunological veterinary medicinal products in the case where the application (grouping) specifically includes a change/changes in the area of active substance production marked as F.I.a.1 - change of manufacturer of starting material/reagent/intermediate used in the production process of the active substance in the production of a biological/immunological product, for several registrations of the same holder.

The evaluation of the mentioned change (grouping) requires one assessment of viral safety and/or TSE risk of the starting material/reagent/intermediate, and the change has no further impact on the quality, safety, and efficacy of the final product. If the applicant intends to submit the same change/changes from category F.I.a.1 for several of their registrations, they should first verify whether it is the above-mentioned case and that ÚSKVBL agrees with their intention and submission of the grouped application.

In such a case, the reimbursement of costs is paid as follows:

* one change with a standard timetable - S (from category F.I.a.1) for multiple marketing authorization numbers - the reimbursement of costs is paid in full for the first marketing authorization number, and the applicant may request a reduction of the reimbursement of costs to the amount of reimbursement of costs corresponding to changes with a reduced timetable - R for all remaining marketing authorization numbers.
* a group of identical changes with a standard timetable - S (from category F.I.a.1) for multiple marketing authorization numbers - the reimbursement of costs is paid in full for the first marketing authorization number, for all requested changes. The applicant may request a reduction of the reimbursement of costs to the amount of reimbursement of costs corresponding to changes with a reduced timetable - R for all identical changes of the remaining marketing authorization numbers.

The reduction of reimbursement of costs cannot be applied in cases where the complexity or scope of the activity performed by ÚSKVBL does not change and only the applicant's system is simplified.

# 6. Reimbursement of Costs for ÚSKVBL Activities Related to the Duration of Medicinal Product Marketing authorization (Annual Maintenance Payments)

**6.1. General Rules**

In accordance with Section 112(2) of the Act on Pharmaceuticals, as amended, the marketing authorization holder pays reimbursements of costs for ÚSKVBL activities related to the duration of veterinary medicinal product marketing authorisation, in the form of annual maintenance payments.

Annual maintenance payments are paid so that by the end of the calendar year, the holder is obliged to pay
the annual maintenance payment for the following calendar year, according to the aforementioned provision.
This means that, for example, in 2024, the holder pays the payment for the year 2025.

If the marketing authorization holder fails to fulfill the obligation to pay this payment within the specified period, ÚSKVBL will invite them to make an additional payment. This payment is due within 15 days of the delivery of the invitation.

If the annual maintenance payment is not paid even within the period specified for additional payment,
the marketing authorization holder is obliged to pay the payment increased by 50%.

The maintenance payment is not paid for the calendar year in which the marketing authorization was granted.

If an annual maintenance fee is paid for the calendar year in which the marketing authorization of the veterinary medicinal product is withdrawn (at the initiative of ÚSKVBL or at the request of the marketing authorization holder), a proportional part of the maintenance fee will be refunded at the request of the marketing authorization holder (see Annex 5). The proportional part is calculated from the paid annual amount by calculating the amount for one month (annual fee: 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 lost its marketing authorization validity for the above reasons is not refunded (e.g., if the product loses its marketing authorization validity on May 3, the refunded part of the annual fee will be for the months of June to December).

**6.2 Payment**

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 data for bank transfer of annual maintenance payments:**

|  |  |
| --- | --- |
| Bank name | Česká národní banka (ČNB) - pobočka Brno |
| Bank address | Rooseveltova, 18631 32, Brno Czech Republic |
| Account number | 35-31229641 |
| Bank code | 0710 |
| IBAN code | CZ76 0710 0000 3500 3122 9641 |
| BIC(originally Swift code) | CNBACZPP |
| Constant symbol | 1148 |
| Variable symbol | Generated by the below specified procedure |
| Payment title | 355 - Research and development |

**When paying the annual maintenance fee, the holder may apply one of the following procedures:**

**a) Separate payment for each medicinal product**

In such a case, the marketing authorization holder obtains the variable symbol for the annual maintenance fee payment as follows:

* the variable symbol is **nine digits long**,
* **the first 3 positions** of the variable symbol represent **the action code**, i.e. **001** (annual maintenance payment) - see Annex 1,
* **the next 4 positions** represent the middle part of the veterinary medicinal product marketing authorization number. The number is always given as four digits, so in the case of a product authorized under marketing authorization number 96/104/07-C, the symbol 0104 is entered (see example below),
* **the last 2 positions** represent the year for which the relevant maintenance payment is paid. Therefore,
if the payment is made, for example, during the year 2024 for the year 2025, the number "25" is entered (see example below).

|  |  |  |
| --- | --- | --- |
| **Action Code** | **Marketing Authorization. Number - Middle Section** | **Year for Which Payment Is Made** |
| **0** | **0** | **1** | **0** | **1** | **0** | **4** | **2** | **5** |

**After making the payment, the holder shall promptly send ÚSKVBL proof of payment (bank statement)
and a completed "Confirmation of Payment of Reimbursement of costs of expert activities performed within
the Scope of ÚSKVBL / for Activities Related to the Duration of Marketing authorization (Annual Maintenance Payment)" form according to Annex 3.**

**b) Collective payment for all medicinal products of the holder**

**This method of payment is only possible if the following rules are observed:**

After making the payment, a cover letter with information about the chosen collective payment method, along with a list of sent documents and any other information for ÚSKVBL, will be sent to ÚSKVBL immediately.

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

* **proof of payment (bank statement),**
* **a completed "Confirmation of Payment of Reimbursement of costs of expert activities performed within the Scope of ÚSKVBL / for Actions Related to the Duration of Marketing authorization (Annual Maintenance Payment)" form according to Annex 3,**
* **a list of all veterinary medicinal products to which the payment is intended, in tabular form, with the product name, registration number, and name of the marketing authorization holder.**

The marketing authorization holder will obtain the variable symbol for the annual maintenance fee payment upon request from ÚSKVBL, specifically at the email address subrtova@uskvbl.cz, or it will be sent to the marketing authorization holder in an information letter about the obligation to pay for actions related to the duration of marketing authorization.

**After verifying the payment and the data of the above-mentioned pre-filled form, ÚSKVBL will send the confirmed form back to the holder. This confirmed form serves as a tax document for the holder.**

In addition to the above details, the general rules specified in section 5.1 of this instruction apply mutatis mutandis to annual maintenance fee payments.

**6.3. Refund of Annual Maintenance Fee**

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

# Annex 1: Price list of Reimbursement of Costs for Expert Activities carried out in the competency of the ÚSKVBL

* ÚSKVBL actions are not subject to reimbursement of expenses if they are required by other state organizational units.
* The provision of administrative information, which is not an expert activity, is governed by Act No. 106/1999 Coll., on the provision of information, as amended.

| **Code for generating the variable symbol** | **Category** | **Amount of costs reimbursement** |
| --- | --- | --- |
| **ANNUAL MAINTENANCE FEE** |
| U - 001**001** | Annual maintenance fee.  | 6 500 CZK |
| **GENERAL** |
| O - 01**01** | Request for provision of hourly oral consultation on request (not related to a previously submitted application). | 2 600 CZK |
| O - 02**02** | Request for issuance of a written expert opinion on request on an issue related to the scope of the institute's activities in the field of veterinary medicines. | 5 400CZK |
| O - 03**03** | Request for issuance of a decision, not related to a previously submitted application, on whether it is a medicinal product, including the distinction between a medicinal product, an active substance, a veterinary medicinal product subject to marketing authorization or another product, or whether it is a homeopathic product. | 7100 CZK |
| **Marketing authorization** |
|   | **NATIONAL MARKETING AUTHORISATION** |   |
| RN - 01**01** | Application for marketing authorization of a veterinary medicinal product – marketing authorization based on complete experimental and/or literature data, including marketing authorization of products with a combination of active substances - veterinary medicinal product for more than two target animal species (national marketing authorization). Applications according to Articles 8, 22, 20 of the VMP Regulation. |  111 100 CZK |
| RN-D - 51**51** | Additional activities that are performed only in cases where applications are submitted that do not contain data and documentation (marketing authorization documentation) that comply with the applicable requirements. | 24 500 CZK |
| RN – 02**02** | Application for marketing authorization of a veterinary medicinal product – marketing authorization based on complete experimental and/or literature data, including marketing authorization of products with a combination of active substances - veterinary medicinal product for max. two target animal species (national marketing authorization). Applications according to Articles 8, 22, 20 of the VMP Regulation. | 85 700 CZK |
| RN-D - 52**52** | Additional activities that are performed only in cases where applications are submitted that do not contain data and documentation (marketing authorization documentation) that comply with the applicable requirements. | 24 500 CZK |
| RN - 03**03** | Application for marketing authorization of a veterinary medicinal product – marketing authorization submitted on the basis of incomplete documentation with reference to the marketing authorization of the original product after the expiration of data protection (generic application). Application according to Article 18 of the VMP Regulation. | 52 400 CZK |
| RN-D - 53**53** | Additional activities that are performed only in cases where applications are submitted that do not contain data and documentation (marketing authorization documentation) that comply with the applicable requirements. | 9 800 CZK |
| RN - 04**04** | Application for marketing authorization of a veterinary medicinal product - hybrid marketing authorization, i.e. marketing authorization submitted on the basis of incomplete documentation with reference to the marketing authorization of the original product after the expiration of data protection, in combination with the submission of own data. Application according to Article 19 of the VMP Regulation. | 75 900 CZK |
| RN-D - 54**54** | Additional activities that are performed only in cases where applications are submitted that do not contain data and documentation (marketing authorization documentation) that comply with the applicable requirements. | 19 600 CZK |
| RN - 05**05** | Multiple application for marketing authorization of a completely identical veterinary medicinal product under a different name (repetition of marketing authorization of a veterinary medicinal product under a different name and possibly for a different holder - duplicate or copy). | 17 600 CZK |
| RN-D - 55**55** | Additional activities that are performed only in cases where applications are submitted that do not contain data and documentation (marketing authorization documentation) that comply with the applicable requirements. | 4 900 CZK |
| RN - 06**06** | Application for marketing authorization of a veterinary medicinal product – marketing authorization submitted on the basis of informed consent of another holder. Application according to Article 21 of the VMP Regulation. | 17 600 CZK |
| RN-D - 56**56** | Additional activities that are performed only in cases where applications are submitted that do not contain data and documentation that comply with the applicable requirements. | 4 900 CZK |
| RN - 07**07** | Changes marked with classification codes G.I.7, G.I.9, G.I.10, G.I.13, G.I.14 and I, including those changes that, by their nature, establish a new veterinary medicinal product according to Czech legislation, i.e. adding strength or dosage form of the product - E (90). | 31 800 CZK |
| RN-D - 57**57** | Additional activities that are performed only in cases where applications are submitted that do not contain data and documentation (marketing authorization documentation) that comply with the applicable requirements. | 4 900 CZK |
| RN–08**08** | Application for marketing authorization of a veterinary medicinal product – marketing authorization of a homeopathic product. Application according to Article 87 of the VMP Regulation. | 48 500 CZK |
| RN - 10**10** | Changes marked with classification codes E, F, G, H - S (60), except for change G.I.18. | 24 000 CZK |
| RN-D - 60**60** | Additional activities that are performed only in cases where applications are submitted that do not contain data and documentation (marketing authorization documentation) that comply with the applicable requirements. | 4 900 CZK |
| RN - 11**11** | VNRA, changes marked with classification codes A, B, C, D (changes not requiring assessment). | 4 900 CZK |
| RN - 12**12** | Changes marked with classification codes E, F, G, H - R (30) and change G.I.18. | 6 860 CZK |
| RN - 14**14** | Application for transfer of marketing authorization of a veterinary medicinal product to another holder. | 4 900 CZK |
| R - 15**15** | Application for cancellation of VMP marketing authorization - without further requirements. | No payment |
| RN - 16**16** | Application for cancellation of marketing authorization of a veterinary medicinal product - with a request for gradual sale. | 2 900 CZK |
|  | **CZ AS REFERENCE MEMBER STATE** |   |
| RRMS/NR -17a**17a** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state – marketing authorizationbased on complete experimental and/or literature data, including marketing authorization of products with a combination of active substances. Case where the veterinary medicinal product is not authorized in the Czech Republic (DCP) and the procedure includes a maximum of 5 CMS. Applications according to Articles 8, 22, 20 of the VMP Regulation. | 197 800 CZK |

|  |  |  |
| --- | --- | --- |
| RRMS/NR -17b**17b** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state - marketing authorization based on complete experimental and/or literature data, including marketing authorization of products with a combination of active substances. Case where the veterinary medicinal product is not authorizedin the Czech Republic (DCP) and the procedure includes a maximum of 6-15 CMS. Applications according to Articles 8, 22, 20 of the VMP Regulation. | 227 200 CZK |
| RRMS/NR -17c**17c** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state – marketing authorization based on complete experimental and/or literature data, including marketing authorization of products with a combination of active substances. Case where the veterinary medicinal product is not authorized in the Czech Republic (DCP) and the procedure includes more than 15 CMS. Applications according to Articles 8, 22, 20 of the VMP Regulation. | 256 500 CZK |
| RRMS/NR-D-67**67** | Additional activities that are performed only in cases where applications are submitted that do not contain data and documentation (marketing authorization documentation) that comply with the applicable requirements. | 24 500 CZK |
| RRMS/R - 18a**18a** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state – marketing authorization based on complete experimental and/or literature data, including marketing authorization of products with a combination of active substances. Case where the veterinary medicinal product has a valid marketing authorization in the Czech Republic (MRP) and the procedure includes a maximum of 5 CMS. Applications according to Articles 8, 22, 20 of the VMP Regulation. | 107 700 CZK |
| RRMS/R - 18b**18b** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state – marketing authorization based on complete experimental and/or literature data, including marketing authorization of products with a combination of active substances. Case where the veterinary medicinal product has a valid marketing authorization in the Czech Republic (MRP) and the procedure includes a maximum of 6-15 CMS. Applications according to Articles 8, 22, 20 of the VMP Regulation. | 137 100 CZK |
| RRMS/R - 18c**18c** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state – marketing authorization based on complete experimental and/or literature data, including marketing authorization of products with a combination of active substances. Case where the veterinary medicinal product has a valid marketing authorization in the Czech Republic (MRP) and the procedure includes more than 15 CMS. Applications according to Articles 8, 22, 20 of the VMP Regulation. | 166 500 CZK |
| RRMS/R-D -68**68** | Additional activities that are performed only in cases where applications are submitted that do not contain data and documentation (marketing authorization documentation) that comply with the applicable requirements. | 14 700 CZK |
| RRMS/NR -19a**19a** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state – marketing authorization submitted on the basis of incomplete documentation with reference to the marketing authorization of the original product after the expiration of data protection (generic application). Case where the veterinary medicinal product is not authorized in the Czech Republic (DCP) and the procedure includes a maximum of 5 CMS. Application according to Article 18 of the VMP Regulation. | 102 300 CZK |
| RRMS/NR -19b**19b** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state – marketing authorization submitted on the basis of incomplete documentation with reference to the marketing authorization of the original product after the expiration of data protection (generic application). Case where the veterinary medicinal product is not authorized in the Czech Republic (DCP) and the procedure includes a maximum of 6-15 CMS. Application according to Article 18 of the VMP Regulation. | 117 000 CZK |

|  |  |  |
| --- | --- | --- |
| RRMS/NR -19c**19c** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state – marketing authorization submitted on the basis of incomplete documentation with reference to the marketing authorization of the original product after the expiration of data protection (generic application). Case where the veterinary medicinal product is not authorized in the Czech Republic (DCP) and the procedure includes more than 15 CMS. Application according to Article 18 of the VMP Regulation. | 131 700 CZK |
| RRMS/NR-D -69**69** | Additional activities that are performed only in cases where applications are submitted that do not contain data and documentation (marketing authorization documentation) that comply with the applicable requirements. | 9 800 CZK |
| RRMS/R-20a**20a** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state – marketing authorization submitted on the basis of incomplete documentation with reference to the marketing authorization of the original product after the expiration of data protection (generic application). Case where the veterinary medicinal product has a valid marketing authorization in the Czech Republic (MRP) and the procedure includes a maximum of 5 CMS. Application according to Article 18 of the VMP Regulation. | 78 300 CZK |
| RRMS/R-20b**20b** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state – marketing authorization submitted on the basis of incomplete documentation with reference to the marketing authorization of the original product after the expiration of data protection (generic application). Case where the veterinary medicinal product has a valid marketing authorization in the Czech Republic (MRP) and the procedure includes a maximum of 6-15 CMS. Application according to Article 18 of the VMP Regulation. | 93 000 CZK |
| RRMS/R-20c**20c** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state – marketing authorization submitted on the basis of incomplete documentation with reference to the marketing authorization of the original product after the expiration of data protection (generic application). Case where the veterinary medicinal product has a valid marketing authorization in the Czech Republic (MRP) and the procedure includes more than 15 CMS. Application according to Article 18 of the VMP Regulation. | 107 700 CZK |
| RRMS/R-D-70**70** | Additional activities that are performed only in cases where applications are submitted that do not contain data and documentation (marketing authorization documentation) that comply with the applicable requirements. | 9 800 CZK |
| RRMS/NR-21a**21a** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state - hybrid marketing authorization, i.e. marketing authorization submitted on the basis of incomplete documentation with reference to the marketing authorization of the original product after the expiration of data protection, in combination with the submission of own data. Case where the veterinary medicinal product is not authorized in the Czech Republic (DCP) and the procedure includes a maximum of 5 CMS. Application according to Article 19 of the VMP Regulation. | 137 600 CZK |
| RRMS/NR-21b**21b** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state - hybrid marketing authorization, i.e. marketing authorization submitted on the basis of incomplete documentation with reference to the marketing authorization of the original product after the expiration of data protection, in combination with the submission of own data. Case where the veterinary medicinal product is not authorized in the Czech Republic (DCP) and the procedure includes a maximum of 6-15 CMS. Application according to Article 19 of the VMP Regulation. | 157 200 CZK |
| RRMS/NR-21c**21c** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state - hybrid marketing authorization, i.e. marketing authorization submitted on the basis of incomplete documentation with reference to the marketing authorization of the original product after the expiration of data protection, in combination with the submission of own data. Case where the veterinary medicinal product is not authorized in the Czech Republic (DCP) and the procedure includes more than 15 CMS. Application according to Article 19 of the VMP Regulation. | 176 700 CZK |
| RRMS/NR-D-71**71** | Additional activities that are performed only in cases where applications are submitted that do not contain data and documentation (marketing authorization documentation) that comply with the applicable requirements. | 19 600 CZK |
| RRMS/R-22a**22a** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state - hybrid marketing authorization, i.e. marketing authoriza-tion submitted on the basis of incomplete documentation with reference to the marketing authorization of the original product after the expiration of data protection, in combina-tion with the submission of own data. Case where the veterinary medicinal product has a valid marketing authorization in the Czech Republic (MRP) and the procedure includes a maximum of 5 CMS. Application according to Article 19 of the VMP Regulation. | 93 000 CZK |
| RRMS/R-22b**22b** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state - hybrid marketing authorization, i.e. marketing authorization submitted on the basis of incomplete documentation with reference to the marketing authorization of the original product after the expiration of data protection, in combination with the submission of own data. Case where the veterinary medicinal product has a valid marketing authorization in the Czech Republic (MRP) and the procedure includes 6-15 CMS. Application according to Article 19 of the VMP Regulation. | 112 600 CZK |
| RRMS/R-22c**22c** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state - hybrid marketing authorization, i.e. marketing authoriza-tion submitted on the basis of incomplete documentation with reference to the marketing authorizationof the original product after the expiration of data protection, in combina-tion with the submission of own data. Case where the veterinary medicinal product has a valid marketing authorization in the Czech Republic (MRP) and the procedure includes more than 15 CMS. Application according to Article 19 of the VMP Regulation. | 132 200 CZK |
| RRMS/R-72**72** | Additional activities that are performed only in cases where applications are submitted that do not contain data and documentation (marketing authorization documentation) that comply with the applicable requirements. | 14 700 CZK |
| RRMS/EX-23a**23a** | Changes marked with classification codes G.I.7, G.I.9, G.I.10, G.I.13, G.I.14 and I, including those changes that, by their nature, establish a new veterinary medicinal product according to Czech legislation, i.e. adding strength or dosage form of the product - E (90), a maximum of 5 CMS are included. | 73 400 CZK |
| RRMS/EX-23b**23b** | Changes marked with classification codes G.I.7, G.I.9, G.I.10, G.I.13, G.I.14 and I, including those changes that, by their nature, establish a new veterinary medicinal product according to Czech legislation, i.e. adding strength or dosage form of the product - E (90), a maximum of 6-15 CMS are included. | 88 100 CZK |
| RRMS/EX-23c**23c** | Changes marked with classification codes G.I.7, G.I.9, G.I.10, G.I.13, G.I.14 and I, including those changes that, by their nature, establish a new veterinary medicinal product according to Czech legislation, i.e. adding strength or dosage form of the product - E (90), more than 15 CMS are included. | 102 800 CZK |
| RRMS/EX-D-73**73** | Additional activities that are performed only in cases where applications are submitted that do not contain data and documentation (marketing authorization documentation) that comply with the applicable requirements. | 7 300 CZK |
| RRMS/CC-24a**24a** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state - multiple application for marketing authorization (MRP/DCP/SRP) of a completely identical veterinary medicinal product under a different name (repetition of marketing authorization of a veterinary medicinal product under a different name and possibly for a different holder - duplicate or copy). Case where the procedure includes a maximum of 5 CMS. | 31 800 CZK |
| RRMS/CC-24b**24b** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state - multiple application for registration (MRP/DCP/SRP) of a completely identical veterinary medicinal product under a different name (repetition of marketing authorization of a veterinary medicinal product under a different name and possibly for a different holder - duplicate or copy). Case where the procedure includes a maximum of 6-15 CMS. | 41 600 CZK |
| RRMS/CC-24c**24c** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state - multiple application for marketing authorization (MRP/DCP/SRP) of a completely identical veterinary medicinal product under a different name (repetition of marketing authorization of a veterinary medicinal product under a different name and possibly for a different holder - duplicate or copy). Case where the procedure includes more than 15 CMS. | 46 500 CZK |
| RRMS/RU-25a**25a** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state - repetition of the mutual recognition procedure (SRP) for a veterinary medicinal product already authorized on the basis of the mutual recognition procedure for a maximum of 5 new CMS. Application according to Article 53 of the VMP Regulation. | 68 500 CZK |
| RRMS/RU-25b**25b** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state - repetition of the mutual recognition procedure (SRP) for a veterinary medicinal product already authorized on the basis of the mutual recognition procedure for a maximum of 6-15 new CMS. Application according to Article 53 of the VMP Regulation. | 78 300 CZK |
| RRMS/RU-25c**25c** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state - repetition of the mutual recognition procedure (SRP) for a veterinary medicinal product already authorized on the basis of the mutual recognition procedure for more than 15 new CMS. Application according to Article 53 of the VMP Regulation. | 83 200 CZK |
| RRMS/NR - 29a **29a** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state – marketing authorization (MRP/DCP/SRP) submitted on the basis of informed consent of another holder. Case where the procedure includes a maximum of 5 CMS. Application according to Article 21 of the VMP Regulation. | 31 800 CZK |
| RRMS/NR - 29b29b | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state – marketing authorization (MRP/DCP/SRP) submitted on the basis of informed consent of another holder. Case where the procedure includes a maximum of 6-15 CMS. Application according to Article 21 of the VMP Regulation. | 41 600 CZK |
| RRMS/ZII-29c**29c** | Application for initiation of the mutual recognition procedure with the Czech Republic as the reference member state – marketing authorization (MRP/DCP/SRP) submitted on the basis of informed consent of another holder. Case where the procedure includes more than 15 CMS. Application according to Article 21 of the VMP Regulation. | 46 500 CZK |
| RRMS/ZII - 26a**26a** | Changes marked with classification codes E, F, G, H - S (60), except for change G.I.18 for a maximum of 5 CMS. | 28 400 CZK |
| RRMS/ZII - 26b**26b** | Changes marked with classification codes E, F, G, H - S (60), except for change G.I.18 for a maximum of 6-15 CMS. | 30 800 CZK |
| RRMS/ZII - 26c**26c** | Changes marked with classification codes E, F, G, H - S (60), except for change G.I.18 for more than 15 CMS. | 33 300 CZK |
| RRMS/ZIB-27**27** | Changes marked with classification codes E, F, G, H - R (30) and change G.I.18. | 7 350 CZK |
| RRMS/ZIA-28**28** | VNRA, changes marked with classification codes A, B, C, D (changes not requiring assessment). | 4 900 CZK |
|  | CZ AS A CONCERNED MEMBER STATE |   |
| RCMS - 30**30** | Application for recognition of a registration decision issued for a medicinal product by the competent authority of another member state – marketing authorization based on complete experimental and/or literature data, including registration of products with a combination of active substances | 94 000CZK |
| RCMS - 31**31** | Application for marketing authorization of a marketing authorization decision issued for a medicinal product by the competent authority of another member state – marketing authorization submitted on the basis of incomplete documentation with reference to the marketing authorization of the original product after the expiration of data protection (generic application). Application according to Article 18 of the VMP Regulation. | 52 400 CZK |

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| RCMS - 32**32** | Application for recognition of a marketing authorization decision issued for a medicinal product by the competent authority of another member state - hybrid marketing authorization, i.e. marketing authorization submitted on the basis of incomplete documentation with reference to the marketing authorization of the original product after the expiration of data protection, in combination with the submission of own data. Application according to Article 19 of the VMP Regulation. | 72 900 CZK |
| RCMS - 33**33** | Changes marked with classification codes G.I.7, G.I.9, G.I.10, G.I.13, G.I.14 and I, including those changes that, by their nature, establish a new veterinary medicinal product according to Czech legislation, i.e. adding strength or dosage form of the product - E (90). | 43 600 CZK |
| RCMS - 34**34** | Application for recognition of a marketing authorization decision issued for a medicinal product by the competent authority of another member state - multiple application for marketing authorization of a completely identical veterinary medicinal product under a different name (repetition of marketing authorization of a veterinary medicinal product under a different name and possibly for a different holder - duplicate or copy). | 26 400 CZK |
| RCMS/ZII-35**35** | Changes marked with classification codes E, F, G, H - S (60), except for change G.I.18. | 24 000 CZK |
| RCMS/ZIB-36**36** | Changes marked with classification codes E, F, G, H - R (30) and change G.I.18. | 5 800 CZK |
| RCMS/ZIA-37**37** | VNRA, changes marked with classification codes A, B, C, D (changes not requiring assessment). | 4 900 CZK |
| RCMS - 38**38** | Application for recognition of a marketing authorization decision issued for a medicinal product by the competent authority of another member state – marketing authorization submitted on the basis of informed consent of another holder. Application according to Article 21 of the VMP Regulation. | 26 400 CZK |
|  | CONCURRENT IMPORT = PARALLEL TRADE |   |
| RSD - 39**39** | Application for authorisation of parallel import of a veterinary medicinal product. | 32 300 CZK |
| RSD - 40**40** | Application for renewal of the authorisation of parallel import of a veterinary medicinal product. | 17 600 CZK |
|  | **APPLICATION FOR ISSUING A CERTIFICATE FOR PHARMACEUTICAL PRODUCT** |  |
| RC - 41**41** | Application for issuing a Certificate for Pharmaceutical Product in the WHO scheme. | 1 700 CZK |
| **INSPECTION** |
|  | MANUFACTURE OF VETERINARY MEDICINAL PRODUCTS |   |
| I - 01**01** | Application for manufacturing authorization or change to the authorization for the manufacture of veterinary medicinal products - for scope import from third countries. | 17 700 CZK |
| I - 02**02** | Application for manufacturing authorization for the manufacture of veterinary medicinal products - for scope non-sterile medicinal products - one pharmaceutically distinct dosage form or one manufacturing unit/line at a single manufacturing site. | 26 900 CZK |
| I - 03**03** | Application for manufacturing authorization or change to the authorization for the manufacture of veterinary medicinal products - for scope non-sterile medicinal products - any other pharmaceutically distinct dosage form and/or manufacturing unit/line. | 13 500 CZK |
| I - 04**04** | Application for manufacturing authorization for the manufacture of veterinary medicinal products - for scope sterile medicinal products - one pharmaceutically distinct dosage form or one manufacturing unit/line at a single manufacturing site. | 42 900 CZK |
| I - 05**05** | Application for manufacturing authorization or change to the authorization for the manufacture of veterinary medicinal products - for scope sterile medicinal products - any other pharmaceutically distinct dosage form or manufacturing unit/line. | 19 800 CZK |
| I - 27**27** | Application for change to the manufacturing authorization for the manufacture of veterinary medicinal products - addition of manufacturer's warehouse. | 8 400 CZK |
| I - 06**06** | Increase of the basic fee in cases where biotechnological or technologically complex manufacture of biological veterinary medicinal products is concerned. | 24 400 CZK |
| I - 07**07** | Application for manufacturing authorization for the manufacture of veterinary medicinal products - for scope separately conducted primary packaging of non-sterile products - one pharmaceutically distinct dosage form and/or one manufacturing unit/line at a single manufacturing site. | 21 000 CZK |
| I - 08**08** | Application for manufacturing authorization or change to the authorization for the manufacture of veterinary medicinal products - for scope separately conducted primary packaging of non-sterile products - any other pharmaceutically distinct dosage form and/or manufacturing unit/line. | 10 500 CZK |
| I - 09**09** | Application for manufacturing authorization for the manufacture of veterinary medicinal products - for scope separately conducted secondary packaging at a single manufacturing site. | 18 100 CZK |
| I - 25**25** | Application for manufacturing authorization or change to the authorization for the manufacture of veterinary medicinal products - for scope separately conducted secondary packaging of non-sterile products - any other manufacturing site. | 8 900 CZK |
| I - 10**10** | Application for change to the manufacturing authorization for the manufacture of veterinary medicinal products without inspection at the manufacturing site. | 2 900 CZK |
| I - 24**24** | Application for manufacturing authorisation (including distribution and export) for transfusion products within the meaning of Section 68a of Act No. 378/2007 Coll., on Pharmaceuticals. | 13 500 Kč |
| I-30**30** | Application for change to manufacturing authorisation for transfusion products within the meaning of Section 68a of Act No. 378/2007 Coll., on Pharmaceuticals. | 9 800 Kč |
| I-31**31** | Application for change to manufacturing authorisation for transfusion products within the meaning of Section 68a of Act No. 378/2007 Coll., on Pharmaceuticals - any other manufacturing site within one authorisation. | 11 000 Kč |
| I-32**32** | Application for change to manufacturing authorisation for transfusion products within the meaning of Section 68a of Act No. 378/2007 Coll., on Pharmaceuticals without inspection at the manufacturing site. | 2 900 Kč |
| I-33**33** | Application for manufacturing authorisation for biological veterinary medicinal products within the meaning of Section 68c of Act No. 378/2007 Coll., on Pharmaceuticals. | 13 500 Kč |
| I-34**34** | Application for change to manufacturing authorisation for biological veterinary medicinal products within the meaning of Section 68c of Act No. 378/2007 Coll., on Pharmaceuticals. | 9 800 Kč |
| I-35**35** | Application for change to manufacturing authorisation for biological veterinary medicinal products within the meaning of Section 68c of Act No. 378/2007 Coll., on Pharmaceuticals - any other manufacturing site within one authorisation. | 11 000 Kč |
| I-36**36** | Application for change to manufacturing authorisation for biological veterinary medicinal products within the meaning of Section 68c of Act No. 378/2007 Coll., on Pharmaceuticals without inspection at the manufacturing site. | 2 900 Kč |
| I-37**37** | Application for manufacturing authorisation - radionuclide generators.  | 13 500 Kč |
| I-38**38** | Application for manufacturing authorisation for products according to Section 25, paragraph 6, letter a) or b) of Act No. 378/2007 Coll., on Pharmaceuticals. | 13 500 Kč |
| I-39**39** | Application for variation to manufacturing authorisation for products according to Section 25, paragraph 6, letter a) or b) of Act No. 378/2007 Coll., on Pharmaceuticals with inspection. | 9 800 Kč |
| I-40**40** | Application for variation to manufacturing authorisation for products according to Section 25, paragraph 6, letter a) or b) of Act No. 378/2007 Coll., on Pharmaceuticals without inspection (administrative changes). | 2 900 Kč |
|  | **WHOLESALE DISTRIBUTION OF VETERINARY MEDICINAL PRODUCTS**  |   |
| I - 11**11** | Application for wholesale distribution authorisation or change to the authorization for the wholesale distribution of veterinary medicinal products - with inspection of one warehouse. | 17 300 CZK |
| I - 12**12** | Application for wholesale distribution authorisation or change to the authorization for the wholesale distribution of veterinary medicinal products - any other warehouse within one application. | 8 400 CZK |
| I - 13**13** | Application for extension of the wholesale distribution authorization for veterinary medicinal products to include the distribution of active substances and excipients - with inspection of one warehouse. | 11 400 CZK |
| I - 14**14** | Application for extension of the wholesale distribution authorization for veterinary medicinal products to include the distribution of active substances and excipients - any other warehouse within one authorisation. | 8 400 CZK |
| I - 15**15** | Application for change to a distribution licence for veterinary medicinal products without inspection. | 2 900 CZK |
|  | **QUALITY CONTROL OF VETERINARY MEDICINAL PRODUCTS** |   |
| I - 16**16** | Application for manufacturing authorisation for veterinary medicinal products - for separately conducted quality control or change to manufacturing authorisation for veterinary medicinal products for separately conducted quality control - conducting partial tests - at one control site. | 16 800 CZK |
| I - 17**17** | Application for manufacturing authorisation for veterinary medicinal products for separately conducted quality control or change to manufacturing authorisation for veterinary medicinal products for separately conducted quality control - testing in a comprehensive scope (chemical/physical, microbiological and biological testing) - at one control site. | 22 700 CZK |
| I - 26**26** | Application for manufacturing authorisation for veterinary medicinal products for separately conducted quality control or change to manufacturing authorisation for veterinary medicinal products for separately conducted quality control - any other control site. | 8 600 CZK |
| I - 18**18** | Application for change to manufacturing authorisation for veterinary medicinal products for separately conducted quality control without inspection at the control site. | 2 900 CZK |
|  | **CERTIFICATION OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICE, CANCELLATION OF AUTHORISATION AT REQUEST, APPLICATION FOR CERTIFICATION OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICE FOR A FOREIGN MANUFACTURER.** |   |
| I - 19**19** | Application for issuing a certificate of compliance with good manufacturing practice or good distribution practice for holders of relevant authorisations and registrations. | 1 300 CZK |
| I - 20**20** | Application for issuing a certificate of compliance with good manufacturing practice in the manufacture of active substances - one manufacturing unit/line. | 27 800 CZK |
| I - 21**21** | Application for issuing a certificate of compliance with good manufacturing practice in the manufacture of active substances - each additional manufacturing unit/line. | 13 000 CZK |
| I - 22**22** | Application for cancellation of an authorisation. | None |
| I - 23**23** | Application for certification of compliance with good manufacturing practice requirements with inspection at a foreign manufacturer ("certificate") according to Section 16(2)(a)(3) of Act No. 378/2007 Coll., on Pharmaceuticals. | Payment according to the required type of inspection increased by 50% + reimbursement of travel and accommodation expenses. |
| **LABORATORY ANALYSES, BATCH RELEASE** |
| L - 01**01** | Batch testing of veterinary medicinal product prior to placing on the market - with submission of a certificate from a European Union member state. | 500 CZK |
| L - 02**02** | Batch testing of veterinary medicinal product prior to placing on the market - without submission of a certificate from a European Union member state. | 1 500 CZK + compensation according to used methods (part B of this appendix) |
| L - 03**03** | Batch release of veterinary medicinal product based on production record assessment, without laboratory analysis - with submitted certificate from a European Union member state - OBPR. | 500 CZK |
| L - 04**04** | Batch release of veterinary medicinal product based on production record assessment, without laboratory analysis - without submission of a certificate from a European Union member state - OBPR. | 1 500 CZK |
| L - 05**05** | Laboratory analysis upon request | Compensation according to used methods (part B of this appendix) |
| **DETERMINATION OF PHARMACOLOGICALLY ACTIVE SUBSTANCE RESIDUES IN BIOLOGICAL MATERIALS** |
| M-01 | Determination of residues in a complex matrix by liquid chromatography with mass spectrometry detection (LC-MS/MS). | 7 300 CZK |
| M-02 | Determination of residues in a complex matrix by gas chromatography with mass spectrometry detection (GC-MS or GC-MS/MS). | 8 000 CZK |
| **CLINICAL TRIALS** |
| K - 01**01** | Application for authorization of a clinical trial of a veterinary medicinal product. | 20 900 CZK |
| K - 02**02** | Application for amendment of the conditions of a clinical trial of a veterinary medicinal product. | 6 900 CZK |
| K - 03**03** | Application for authorization of a verification clinical trial of a veterinary medicinal product. | 75 900 CZK |
| K - 04**04** | Application for amendment of the conditions of a verification clinical trial of a veterinary medicinal product. | 6 900 CZK |
| K - 05**05** | Approval of a non-interventional post-marketing authorization veterinary study. | No fee |
| K - 06**06** | Application for amendment of an approved non-interventional post-marketing authorization veterinary study. | No fee |
| **ACTIVITIES WITHIN THE EUROPEAN UNION** |
| E - 01**01** | Application for the performance of expert activities submitted by the European Medicines Agency (EMA)\*. | 577 CZK |
| E - 02**02** | Professional acts performed at the request of the European Directorate for the Quality of Medicines & HealthCare (EDQM). | In accordance with the contractual arrangement between ÚSKVBL and EDQM. |

\* the price per unit of calculation for the Czech Republic, is determined by the EMA.

# Schedule of reimbursement of expenses for laboratory analyses of medicinal products and excipients performed under the authority of ÚSKVBL.

|  |  |  |
| --- | --- | --- |
| **Item** | **Test** | **Amount of costs reimbursement** |
| **Physiochemical tests** |
| 1 | Appearance | 450 CZK |
| 2 | Particle size determination |  |
| 2a | *Microscopically* | 1 800 CZK |
| 2b | *Sieving - 1 sieve* | 1 390 CZK |
| 2c | *For each additional sieve, add to item 2b* | 280 CZK |
| 3 | Airtightness | 290 CZK |
| 4 | Solubility determination | 550 CZK |
| 5 | Loss on drying | 1 970 CZK  |
| 6 | Karl Fisher titration | 3 410 CZK |
| 7 | Dry matter determination, residue on evaporation | 1 100 CZK |
| 8 | Ash determination |  |
| 8a | *Total ash* |  2 600 CZK |
| 8b | *Sulphated ash or more complex ashing* |  2 950 CZK |
| 9 | Melting point determination instrumentally |  870 CZK |
| 10 | Density determination  |  |
| 10a | *Pycnometrically* |  1 070 CZK |
| 10b | *Hydrometer* |  1 090 CZK |
| 11 | Viscosity determination by rotational viscometer |  1 700 CZK |
| 12 | Refractive index determination (refractometry) |  1 000 CZK |
| 13 | Spectrophotometric determination |  4 750 CZK |
| 14 | Titration determination |  2 240 CZK |
| 15 | pH measurement (electrometrically) |  810 CZK |
| 16 | Electrical conductivity measurement |  810 CZK |
| 17 | Thin layer chromatography |  3 880 CZK |
| 18 | High performance liquid chromatography |  |
| 18a | *1 analyte* |  7 260 CZK |
| 18b | *1 analyte in two sample* |  8 980 CZK |
| 18c | *1 analyte in two or more samples, item increases by* |  1 750 CZK |
| 18d | *1 analyte - 3 samples* |  10 730 CZK |
| 18e | *1 analyte - 4 samples* |  12 480 CZK |
| 18f | *2 analytes in one determination* |  10 440 CZK |
| 18g | *3 or more analytes in 1 determination* |  13 670 CZK |
| 19 | Gas chromatography |  6 500 CZK |
| 20 | Color and precipitation reactions |  790 CZK |
| 21 | Clarity and opalescence of liquids (visually) |  1 270 CZK |
| 22 | Degree of coloration of liquids (visually) |  1 370 CZK |
| 23 | Pepsin activity determination | 6 270 CZK |
| 24 | Dissolution - UV/VIS | 7 380 CZK |
| 25 | Dissolution - HPLC |  8 190 CZK |
| 26 | Average mass and mass uniformity | 770 CZK |
| 27 | Tablet friability | 1 230 CZK |
| 28 | Tests for identity of ions and groups |  550 CZK |
| 29 | Disintegration test of tablets and capsules (without determination) |  |
| 29a | Disintegration in water | 1 870 CZK |
| 29b | Disintegration in gastric juice | 2 320 CZK |
| 29c | Disintegration in duodenal juice | 2 420 CZK |
| 30 | Test for recoverable volume of parenteral preparations | 860 CZK |
| **MIKROBIOLOGICAL AND BIOLOGICAL TESTS** |
| 31 | Sterility test | 9 100 CZK |
| 32 | Microbiological testing of non-sterile products (total viable aerobic count) |  |
| 32a | Microbiological testing of non-sterile products - preparations for topical use (dermal, nasal, aural administration, etc.) | 4 900 CZK |
| 32b | Microbiological testing of non-sterile products - preparations for oral administration | 4 600 CZK |
| 32c | Microbiological testing of non-sterile products - preparations containing raw materials of natural origin that cannot be antimicrobially treated | 6 100 CZK |
| 32d | Microbiological testing of non-sterile products - premixes for medicated feed for veterinary use with excipients that cannot be antimicrobially treated | 5 900 CZK |
| 32e | Microbiological testing of non-sterile products for vaginal administration | 4 900 CZK |
| 33 | Microbiological assay of antibiotics by diffusion plate method | 4 100 CZK |
| 34 | Viable count determination in live bacterial vaccines | 2 700 CZK |
| 35 | Bacterial count determination of probiotic strains | 2 700 CZK |
| 36 | Bacterial strain identification | 1 400 CZK  |
| 37 | Exclusion of bacterial and fungal contamination | 3 700 CZK |
| 38a | Mycoplasma test - culture | 7 800 CZK |
| 38b | Mycoplasma test - PCR | 5 300 CZK  |
| 39 | Bacterial endotoxins | 3 100 CZK |
| 40 | Potency determination of inactivated rabies vaccine for veterinary use by NIH test | 43 300 CZK |
| 41 | Potency determination of equine influenza vaccine in guinea pigs (HIT) | 18 500 CZK |
| 42 | Potency determination of swine erysipelas vaccine in mice - by ELISA antibody increase determination | 14 300 CZK |
| 43 | Virus titer determination by microtitration method in cell cultures in live viral vaccines - general (e.g. myxomatosis) | 10 000 CZK |
| 44 | Potency determination of inactivated rabies vaccine for veterinary use by serological method with immunofluorescence detection | 22 000 CZK |
| 45 | Virus titer determination of Newcastle disease of poultry in chicken embryos | 11 100 CZK |
| 46 | Hyphal count determination in vaccines | 1 500 CZK |
| 47 | Infectious bursal disease virus titer determination | 10 300 CZK |
| 48 | Rabies virus titer determination by microtitration method | 12 200 CZK |
| 49 | Test for the presence of viral agent by PCR method | 4 700 CZK |
| 50 | Test for the presence of viral agent by qPCR method | 4 700 CZK |
| 51 | Potency determination of avian or bovine tuberculin PPD | 31 400 CZK |
| 52 | Sensitization test - avian or bovine tuberculin PPD | 19 400 CZK |
| 53 | Glycoprotein determination in inactivated rabies vaccines by ELISA method | 10 500 CZK |
| 54 | Infectious bovine rhinotracheitis (IBR) virus titer determination by microtitration method | 9 900 CZK |
| 55 | Potency determination of inactivated infectious bovine rhinotracheitis (IBR) vaccines in guinea pigs by ELISA method, gE antibody detection | 21 800 CZK |
| **Batch testing of immunological veterinary medicinal products** |
| OC - 01 | Control of inactivated swine erysipelas vaccine (appearance, efficacy - ELISA) | 14 750 CZK |
| OC - 02 | Control of live swine erysipelas vaccine (appearance, solubility, viable count, purity, strain typing) | 6 700 CZK |
| OC - 03 | Control of live oral rabies vaccine for foxes (appearance, virus titer on cell culture) | 12 650 CZK |
| OC - 04 | Control of inactivated rabies vaccine for veterinary use (appearance, efficacy) by NIH test | 43 750 CZK |
| OC- 05 | Control of equine influenza vaccine (appearance, efficacy) | 18 950 CZK |
| OC - 06 | Control of inactivated rabies vaccine for veterinary use (appearance, serological efficacy determination) | 22 450 CZK |
| OC - 07 | Control of diagnostic preparation containing avian or bovine tuberculin (appearance, sensitization, efficacy) | 51 250 CZK |
| OC - 08 | Control of inactivated rabies vaccine for veterinary use (appearance, glycoprotein determination) | 10 950 CZK |
| OC - 09 | Control of live infectious bovine rhinotracheitis (IBR) vaccine for veterinary use (appearance, virus titer determination) | 10 350 CZK |
| OC - 10 | Control of inactivated infectious bovine rhinotracheitis (IBR) vaccine for veterinary use (appearance, efficacy, gE antibody detection) | 22 250 CZK |

# Annex 2: Doklad o zaplacení správního poplatku/ *Proof of payment of administration fees*

 **Č.j./ *Ref.No.***

 **Žadatel** = **Dosavadní držitel rozhodnutí o registraci/Veterinární lékař**

 **Applicant = Current marketing authorization decision holder/Veterinary doctor**

 Název (společnosti nebo jméno veterinárního lékaře) / (Company/Veterinary doctor) Name:

 Adresa / Address:

 Země / Country:

 IČO:

 DIČ:

 ID DS:

 **Osoba zmocněná k jednání dosavadním držitelem rozhodnutí o registraci4)**

 **Person authorised for communication on behalf of the current marketing authorization decision holder4)**

 Jméno / Name:

 Adresa / Address:

 Země / Country:

 Telefon / Telephone:

 E-Mail:

ID DS (pro ČR) pro zaslání dokladu:

|  |  |  |
| --- | --- | --- |
| **Typ žádosti /*Type of Application*** | **Kč** |  |
| Žádost / *Application for (on)* |  |  |
| **- o vydání osvědčení** výrobci veterinárních přípravků o splnění požadavků SVP/ *on the issuance of a certificate to manufacturers of veterinary preparations on compliance with the requirements of the GMP* | **2000,-** |[ ]
| - **o** **registraci** veterinárního léčivého přípravku, včetně zvykového rostlinného veterinárního léčivého přípravku nebo homeopatického přípravku / *marketing authorisation of a veterinary medicinal product, including a herbal veterinary medicinal product or homeopathic product* | **2000,-** |[ ]
| - **o změnu** rozhodnutí o registraci veterinárního léčivého přípravku, včetně homeopatického přípravku, záznam změny VRNA do databáze Unie/podání změny typu VRA /*variation to a marketing authorisation of a veterinary medicinal product, including homeopathic product, records of variation VNRA to UPD* | **2000,-** |[ ]
| - **o převod** registrace veterinárního léčivého přípravku, včetně homeopatického přípravku / *Application for transfer of a marketing authorisation of a veterinary medicinal product, including homeopathic product* | **2000,-** |[ ]
| - o povolení souběžného dovozu = paralelního obchodu veterinárního léčivého přípravku, včetně homeopatického přípravku /*Application for parallel trade of a veterinary medicinal product, including homeopathic product* | **2000,-** |[ ]
| - **o zrušení** rozhodnutí o registraci veterinárního léčivého přípravku, včetně homeopatického přípravku / *Application for withdrawal of a marketing authorisation of a veterinary medicinal product, including 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/*a decision in cases of doubt as to whether the product is a veterinary medicinal product or a medicinal substance or a medicinal product subject to a marketing authorisation or another product, or whether it is a veterinary homeopathic medicinal 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**) /*an authorisation for the placing on the market and use of a veterinary medicinal product not authorised in the European Union or in a third country (****veterinary special treatment programme****)* | **2000,-** |[ ]
| **- o schválení** **klinického hodnocení nebo ověřovacího klinického hodnocení** veterinárního léčivého přípravku/an *authorisation of a clinical trial or a validation clinical trial of a veterinary medicinal product* | **2000,-** |[ ]
| Žádost / *Application for* |  |  |
| - o povolení či změnu povolení k výrobě veterinárních léčivých přípravků/ *granting or variation to a manufacturing authorisation for veterinary medicinal products*  | **2000,-** |[ ]
| - o povolení nebo změny povolení výroby veterinárních transfuzních přípravků nebo biologických veterinárních léčivých přípravků/*granting or variation to a manufacturing authorisation for veterinary transfusion products or biological veterinary medicinal products* | **2000,-** |[ ]
| - o povolení nebo změnu povolení výroby v zařízení transfúzní služby | **2000,-** |[ ]
| - o povolení či změnu k výrobě veterinárních léčivých přípravků - veterinárních autogenních vakcín / *granting or variation to a manufacturing authorisation for veterinary autogenous vaccines* | **2000,-** |[ ]
| - o povolení či změnu povolení k činnosti kontrolní laboratoře / *granting or variation to a licence for control laboratories/granting or variation to a manufacturing authorisation in a transfusion service facility* | **2000,-** |[ ]
| Žádost / *Application for* |  |  |
| - o povolení či změnu povolení k distribuci léčivých přípravků / *granting or variation to a distribution authorisation for veterinary medicinal products* | **2000,-** |[ ]
| - o rozšíření povolení k distribuci / *extension of a distribution authorisation* | **2000,-** |[ ]
| Vydání stejnopisu, opisu, kopie, fotokopie nebo výpisu/ *Issue of a certified copy, true copy, copy, photocopy or abstract* |  |  |

**Datum Podpis žadatele, popř. jím zmocněné osoby**

***Date* *Signature of the applicant, or person authorized by him***

 Jméno, příjmení / *First name, Family Name*:

 Adresa / *Address*:

|  |
| --- |
| Application Reference Number: Received at ÚSKVBL on: Name/Signature:  |
| PAYMENT RECEIPT CONFIRMATIONPayment by bank transfer - statement number: Statement date: …………………………………. …………………………………. …………………………………… **Date Organizational Unit of ÚSKVBL Name/Signature** |

# Annex 3: Confirmation of payment of reimbursement of costs of expert activities performed under the authority of ÚSKVBL / for acts related to the duration of registration (annual maintenance fee).

**(TAX DOCUMENT)**

|  |
| --- |
| **Applicant -** name, address**Contact address**- name, address, telephone, fax, e-mail (fill it in only if it differs from the authorised person ‘s address) |
| **Authorised person** - name, address**Contact address** - name, address, telephone, fax, e-mail |
| **The name of the veterinary medicinal product,** pharmaceutical form, strength (don ‘t fill in cases of inspection, lab analyses or clinical trial approval) |
| **Application for (complete according to the Guideline USKVBL/UST - 4/2008 Rev.3)** |
| Code of activity | Activity |
|  |  |

**Variable symbol (cross the possibility our payment relates to and fill in the variable symbol):**

**[ ]  activities connected with MA**:

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

**[ ]** [ ] **[ ] [ ] [ ] [ ]  annual maintenance fee:**

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

**[ ]  activities connected with inspection, lab analysis and clinical trials**:

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

|  |
| --- |
| Paid by a bank transferAmount paid in CZK: Date of order to pay:  |
| **The person remitting the amount** (cross out the person who remits the amount to the USKVBL) - **payer**:  |
| [ ]  Applicant/MA holder | [ ]  Authorised person |
| **The person to receive** Certificate of payment of the costs for expert activities carried out on request confirmed by the USKVBL (cross out the person to whom it will be sent) |
| [ ]  Applicant/MA holder | [ ]  Authorised person |
| The name of the bank providing thetransaction: | The payer ‘s bank account number: | Constant symbol: |

|  |
| --- |
| Filled in by registry of the USKVBL: Application reference number:Accepted at the USKVBL on: Name/Signature:  |
| CONFIRMATION OF RECEIVING THE PAYMENTBank transfer payment - number of statement: Date of statement: …………………………………. …………………………………. …………………………………… **Date Department of the USKVBL Name/Signature** |

# Annex 4: Application for administrative fee refund

Institute for State Control of Veterinary Biologicals and Medicines

Hudcova 232/56a

621 00 Brno

Czech Republic

**Application for administrative fee refund**

|  |  |
| --- | --- |
| Application Ref. no. / File ID: |  |
| Type of application: |  |
| Product name (in case of MA application): |  |
| Specification of the application content |  |
| Name of the applicant: |  |
| Address of the applicant: | street, P.O. BOX: | City, ZIP Code, country: |
| Contact person: |  |
| Address of the contact person:  |  | Telephone: |
| Paid amount in CZK: |  | Payment date: |
| Variable symbol of the application: |  | Currency for the refund: |
| Applicant ´s bank name: |  | Address: |
| Applicant ´s bank account no/bank code:  |  | IBAN: |
| Swift /if known: |  | National clearing code (if known): |
| Rationale for the requested refund: |  |
| Source reference where the statement could be checked |  |

--------------------------------- -----------------------------------------------------

Date Applicant ´s name and signature

 stamp

|  |
| --- |
| ***Do not complete - for the ÚSKVBL ´s internal use***Administrative fee refund is/is not in compliance with the § 7 of the Act on Administrative fees:- Reimbursed administrative fee is not listed in the price list or was reimbursed by a person who is not a payer or administrative fee overpaidI agree/disagree with the refund of the amount of: ……………………… CZK Date Name and signature of a section managerDecision under the ref. No …………… issued on …………, the ÚSKVBL decided ona) completely refund of the administrative feeb) partially refund of the administrative fee in an amount ……………c) refusal of the application for the administrative fee refund Date Name and signature of an economical section manager  |

# Annex 5: Application for refunds of costs reimbursement

Institute for State Control of Veterinary Biologicals and Medicines

Hudcova 232/56a

621 00 Brno

Czech Republic

**Application for refunds of costs reimbursement**

|  |  |
| --- | --- |
| Application Ref. no. / File ID: |  |
| Expert activity: |  |
| Activity code: |  |
| Product name (in case of MA application): |  |
| Specification of the application content: |  |
| Name of the applicant: |  |
| Address of the applicant: | street, P.O. BOX: | City, ZIP Code, country: |
| Contact person: |  |
| Address of the contact person:  |  | Telephone: |
| Paid amount in CZK: |  | Payment date: |
| Variable symbol of the application: |  | Currency for the refund: |
| Applicant ´s bank name: |  | Address: |
| Applicant ´s bank account no/bank code:  |  | IBAN: |
| Swift /if known: |  | National clearing code (if known): |
| Rationale for the requested refund: |  |
| Source reference where the statement could be checked |  |

--------------------------------- -----------------------------------------------------

Date Applicant ´s name and signature

stamp

|  |
| --- |
| ***Do not complete - for the USKVBL ´s internal use***Checking of information mentioned the rationale:Statement of a department carrying out the expert activity:Decision - section manager: ----------------------------- ------------------------------------------------- Date Name and signature of a section manager Notes of the economical section: ----------------------------- ------------------------------------------------------------- Date Name and signature of an economical section manager  |

1. \* This situation concerns states that are not members of the EU or the European Economic Area (EEA), nor have they signed an accession agreement or an agreement on the recognition of Good Manufacturing Practice (GMP) inspection findings (Mutual Recognition Agreement, MRA) with the EU. At the time of issuing this instruction, functional MRA agreements are in place with Canada, Switzerland, New Zealand, and Australia. [↑](#footnote-ref-1)