UST-29 version 15 Administrative fees, reimbursements of costs of expert activities, reimbursements of activities associated with the provision of information and reimbursements of other activities

This guideline supersedes guideline UST-29 version 14 effective as of 1 August 2015.

Introduction

The guideline is being issued in compliance with the provisions of Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts, as amended (hereinafter referred to as the "Act on Pharmaceuticals"), of Act No 48/1997 Coll., on Public Health Insurance and on Amendments to Some Related Acts (hereinafter referred to as the "Act on Public Health Insurance"), of Act No 634/2004 Coll., on Administrative Fees, as amended (hereinafter referred to as the "Act on Administrative Fees"), of Act No 106/1999 Coll., on Free Access to Information, as amended (hereinafter referred to as the "Act on Free Access to Information"), of Act No 257/2001 Coll., on Libraries, as amended (hereinafter referred to as the "Act on Libraries"), of Act No 218/2000 Coll., on Budgetary Rules, as amended (hereinafter referred to as the "Act on Budgetary Rules") and of Act No 268/2014 Coll., on Medical Devices and on Amendment to Act No 634/2004 Coll., on Administrative Fees, as amended (hereinafter referred to as the "Act on Medical Devices").

The State Institute for Drug Control (hereinafter referred to as "SÚKL") has, within the scope of a revision of guideline UST-29, amended the possibility of discount for micro, small and medium enterprise for items in the Pricelist of reimbursements of costs of expert activities and annual maintenance fees pursuant to Decree No 427/2008 Coll., stipulating the amounts of reimbursement of costs of expert activities conducted within the scope of powers of the State Institute for Drug Control and the Institute for the State Control of Veterinary Biologicals and Medicaments, as amended (the "reimbursement decree"), and the process when the duty of annual maintenance fee payment pursuant to Section 112 of the Act on Pharmaceuticals on Pharmaceuticals, is not fulfilled.

1 Payment of administrative fees

1.1 Procedure to be applied in the payment of administrative fees

Pursuant to the provisions of the Act on Administrative Fees, applicants shall be obliged to pay administrative fees for the submission of applications.

For the submission of the following applications:	Administrative fee amount	Remark
Application:		
• For marketing authorisation of a medicinal product, variation to or renewal of marketing authorisation of a medicinal product	**2 000 CZK**	
• For transfer of marketing authorisation or authorisation of parallel import of a medicinal product	**2 000 CZK**	
• For revocation of a marketing authorisation of a medicinal product	**1 000 CZK**	
Application:		
• For registration of a homeopathic product, variation to or renewal of the registration of a homeopathic product or transfer of registration of a homeopathic product	**2 000 CZK**	
• For authorisation of parallel import of a homeopathic product	**2 000 CZK**	
• For revocation of registration of a homeopathic product	**1 000 CZK**	
Application:		
• For manufacturing authorisation of medicinal products or variation thereto	**2 000 CZK**	
• For authorisation to engage in the activities of a control laboratory or variation thereto	**2 000 CZK**	
• For authorisation of manufacture in a blood centre or variation thereto	**2 000 CZK**	
Application:		

• For distribution authorisation for medicinal products or variation thereto	**2 000 CZK**	
• For extension of distribution authorisation	**2 000 CZK**	
Application for the determination of the maximum price or amounts and conditions of reimbursement of a medicinal product or foodstuffs for special medical purposes:		
• New active substance, new combination of active substances, new indication, new pharmaceutical form intended for new indications	**20 000 CZK**	
• New pharmaceutical form without denomination for new indications, new strength	**10 000 CZK**	
• Generic products or new pack sizes	**8 000 CZK**	
• Others	**10 000 CZK**	
• Foodstuffs for special medical purposes	**10 000 CZK**	
• Medicinal products included in the registry of orphan medicinal products	**0 CZK**	
Application:		
• For variation to the decision on the established maximum price or amount and conditions of reimbursement due to extended indications, restriction of existing terms of reimbursement or increased reimbursement	**20 000 CZK**	
• For variation to the decision on the established maximum price and amount and conditions of reimbursement in other cases	**10 000 CZK**	
Provision of a counterpart, copy, photocopy, or excerpt from official files, registries, registers, records, files and documents or any other written or picture materials, or notice of a negative finding	**50 CZK**	For each page, incl. incomplete pages
Provision of a counterpart, copy, photocopy, or excerpt from official files, registries, registers, records, files and documents or any other written or picture materials, or notice of a negative finding	**40 CZK**	On the technical data medium
Provision of a counterpart, copy, photocopy, or excerpt from official files, registries, registers, records, files and documents or any other written or picture materials, or notice of a negative finding	**15 CZK**	For first page and 5 CZK for each page, incl. incomplete pages, if made using a photocopier or a PC printer
Issue of certified output from public administration information system	**100 CZK**	For the first page and 50 CZK for each new page

Administrative fees shall be paid by bank transfer.

The variable symbol of the payment may be obtained by the applicant using interactive forms:

a) The form for the payment of administrative fees covering the costs of expert activities conducted upon request is available from **http://www.sukl.cz/modules/sukl/payment.php,, section Pricelist and Fees**.
b) Forms for individual activities available from **http://www.sukl.cz/pokyny-a-formulare-10, section SÚKL activities – Price and reimbursement rating for pharmaceuticals** shall be used for the payments of administrative fees for applications for the determination of maximum manufacturer's price and/or amount and conditions of reimbursement of a medicinal product or foods for special medical purposes.

In the interactive form, the applicant shall complete the required data relevant to the application. Once these are posted (from the web) to the administrative authority, the “Proof of payment of Administrative Fee” will be automatically generated for the applicant. The document has to be printed directly from the web browser. The document contains the variable symbol of the payment allocated to the application by the SÚKL identification system.
The applicant shall use the allocated variable symbol for the identification of the payment by bank transfer.
The amount is stated in Czech Crowns. When making the payment it is necessary to inform the bank that the payment must be transferred to the SUKL account in the required currency and full amount and any costs of bank transfer/service charges shall be borne by the payer.

The requested activity cannot be carried out, if the payment does not show the allocated variable symbol! Pursuant to the Act on Administrative Fees, the applicant shall be sent an invitation to pay the fee within the timeline of 15 days. If the applicant fails to evidence the payment of the administrative fee (made with the allocated variable symbol) within the determined period, the administrative procedure will be suspended.
SÚKL details for bank transfers of administrative fee payments:

Name of the bank	Česká národní banka
Address of the bank	Na Příkopě 28/3181 Praha 1 115 03 Czech Republic
Account number	3711-623101
Bank code	0710
IBAN	CZ35 0710 0037 1100 0062 3101
BIC (originally SWIFT)	CNBACZPP
Constant symbol	1148
Variable symbol	Generated by the below specified procedure in a manner preventing any duplicities in variable symbols.

In exceptional cases, the administrative fee may be paid cash at the cash desk of the Institute or by revenue stamps (up to the amount of 5,000 CZK).
If the applicant does not have the opportunity to complete the interactive form, the document may be obtained from SÚKL mail room (Annex 2 refers).

1.2 Administrative fee refunds

Paid administrative fees may be refunded only for reasons stipulated by the Act on Administrative Fees (section 7).
If any of the statutory reasons for administrative fee refund arises, and the applicant files a request for refund, SÚKL shall decide about this request. The request should be filed using the "Request for Administrative Fee Refund" form (Annex 5).

Refunds of administrative fees paid by means of revenue stamps shall be made by SÚKL likewise (Section 7, paragraph 5 of the Act on Administrative Fees).

2 Reimbursements of costs of expert activities and annual maintenance fees

2.1 The procedure to be applied to the reimbursements of costs of activities conducted upon request and payments of annual maintenance fees

Pursuant to Section 112 of the Act on Pharmaceuticals, SÚKL collects reimbursements for expert activities conducted upon request and annual maintenance fees. This legal regulation allows SÚKL to collect the reimbursements in advance. The reimbursement of costs is payable before the submission of the application and shall be made by **bank transfer**, exceptionally cash at the cash desk, in the amount stipulated by the Pricelist (see Annex 1, part A).
The amount is stated in Czech Crowns. When making the payment it is necessary to inform the bank that the payment must be transferred to the SUKL account in the required currency and full amount and any costs of bank transfer/service charges shall be borne by the payer.
When paying the annual maintenance fee, the interactive form shall be used as for the reimbursement of costs. This payment is made without any submission of an application and proof of payment shall not be sent. The Institute, having verified the accuracy of the payment, shall send a proof of payment of the annual maintenance fee to the payer.

SÚKL details for bank transfers for the reimbursement of costs for expert activities:

Name of the bank	Česká národní banka
Address of the bank	Na Příkopě 28/3181 Praha 1 115 03 Czech Republic
Account number	35-623101
Bank code	0710
IBAN	CZ94 0710 0000 3500 0062 3101
BIC (originally SWIFT)	CNBACZPP

Constant symbol	0308
Variable symbol	Generated by the below specified procedure in a manner preventing any duplicities in variable symbols.

The document is generated automatically when the **interactive form** available from **http://www.sukl.cz, section Pricelist and Fees** is completed.

The applicant shall complete the required data in the interactive form. Once the form is posted, the "Proof of Payment of Costs for Expert Activities Conducted upon Request" is generated, which has to be printed directly from the internet browser. This document shows the generated **variable symbol to be used for the payment of costs of expert activities associated with the application in question.** For more detailed instructions please refer to the website mentioned above.
If the applicant does not have the opportunity to complete the interactive form, it is possible to obtain it from the SÚKL mail room (Annex 3).

Attachments to the application for an expert activity:

- **Completed "Proof of Payment of Administrative Fee"** form in one copy* (as per part 1 of the Guideline), only where the expert activity within the procedure is subject to an administrative fee.

- **Completed "Proof of Payment of Costs for Expert Activities Conducted upon Request"** form in one copy* (as per part 2 of the Guideline).

** if submitted in hard copy.*

- **Document evidencing that the costs have been reimbursed as per the Pricelist and a document evidencing that the administrative fee has been paid** (where the Act stipulates that the reimbursement forms part of the particulars of the application) – where a non-cash transfer is concerned, this document shall be a copy of the payment order endorsed by the bank or a copy of the statement of account; if the reimbursement is paid cash at the cash desk, SÚKL cashier shall endorse the payment of costs directly in the "Proof of Payment of Costs for Expert Activities Conducted upon Request" form and the payment of the administrative fee directly in the "Proof of Payment of Administrative Fee" form.

2.2 Waivers and refunds of cost reimbursements

The procedure applicable to the situation when the Institute waives the reimbursement of costs or refunds parts thereof is provided in SÚKL guideline UST-24 - Waiver and refunds of reimbursement of costs for expert activities conducted upon request.

3. Reimbursement of costs for activities associated with the provision of information

With regard to the provision of information as stipulated by Section 17 of the Act on Free Access to information, SÚKL shall be authorised to request reimbursement in the amount of costs associated with the making of copies, procurement of technical data carriers and with the sending of information to the applicant and reimbursement for extraordinarily extensive retrieval of information, and, as stipulated by Section 4 of the Act on Libraries, SÚKL shall be authorised to request reimbursement of actually incurred costs for the provision of library and information services.
The amounts of reimbursements of costs associated with the provision of information and library and information services are provided in the Pricelist (Annex 1, part D).
In case of reimbursement of costs of a request for the provision of information filed pursuant to the Act on Free Access to Information, SÚKL shall announce in writing to the applicant that it will require a payment for the provision of information as well as the amount of such payment. The advice shall clearly indicate on the basis of what facts and through what method the Institute has arrived at the amount of the payment, and SÚKL shall send an invoice for the required amount to the applicant.

SÚKL details for bank transfers for the reimbursement of costs for activities associated with the provision of information and library and information services:

Name of the bank	Česká národní banka
Address of the bank	Na Příkopě 28/3181 Praha 1 115 03 Czech Republic
Account number	35-623101

Bank code	0710
IBAN	CZ94 0710 0000 3500 0062 3101
BIC (originally SWIFT)	CNBACZPP
Constant symbol	0308
Variable symbol	by invoice

4. Reimbursement of other activities

Pursuant to Section 6 of the Act on Budgetary rules, SÚKL shall collect reimbursement of costs associated with the rent of the property of the Czech Republic which it administers.
The amounts of reimbursements of these costs are provided in the Pricelist (Annex 1, part E). The services shall be provided on the basis of a binding written request signed by the applicant (an electronic request sent by e-mail to posta@sukl.cz shall be considered binding only if signed by a certified electronic signature, any other case shall be regarded a preliminary request which shall be binding and considered only after the delivery of a written signed request) specifying the required service. After the service is provided, SÚKL shall issue an invoice and send it to the applicant; the invoice shall show data necessary for the bank transfer (variable symbol, bank details for SÚKL). Costs may also be reimbursed by a cash payment made at the cash desk.

SÚKL details for bank transfers for the reimbursement of costs for other activities:

Name of the bank	Česká národní banka
Address of the bank	Na Příkopě 28/3181 Praha 1 115 03 Czech Republic
Account number	19-623101
Bank code	0710
IBAN	CZ19 0710 0000 1900 0062 3101
BIC (originally SWIFT)	CNBACZPP
Constant symbol	0308
Variable symbol	by invoice

5. Payments for reimbursement of costs of expert activities pursuant to the Act on Medical Devices

5.1 Procedure to be employed in the payment for reimbursement of costs of activities performed upon request and annual maintenance fees

Pursuant to Section 94, paragraph 1 of Act on Medical Devices, SÚKL shall claim reimbursement of costs for expert activities performed upon request. This legal regulation allows SÚKL to charge adequate compensation of costs in advance, the amount of compensation which needs to be reimbursed prior to the submission of the application being as outlined by Annex F. The applicant shall be obliged to generate a proof of payment of the amount using an interactive form in compliance with the rules set forth by the Pricelist (Annex 1, section F). Where the applicant has doubts regarding the amount of compensation, the anticipated timescale of the expert activities may be discussed in advance with the Institute.

The payment for reimbursement of costs shall be made by the applicant by means of a bank transfer using the generated variable symbol prior to the submission of the application. The amount of the payment is determined in Czech crowns. With a view to this, when making the payment, it is necessary to enter in the bank that the payment is to be transferred to SÚKL's account in the required amount and currency and that bank fees are to be charged to the payer.

SÚKL details for bank transfers of reimbursement of costs of expert activities:

Name of the bank	**Česká národní banka**
Address of the bank	**Na Příkopě 28/3181** **Praha 1** **115 03** **Česká republika**
Account number	**10030 - 623101**
Bank code	**0710**

IBAN	**CZ40 0710 0100 3000 0062 3101**
BIC (originally SWIFT)	**CNBACZPP**
Constant symbol	**0308**
Variable symbol	**Generated by the process described below**

The document is automatically generated when the **interactive form** available from **http://www.sukl.cz**, **section Pricelist and fees,** is completed.

The applicant shall complete the required data in the interactive form. Following submission, the "Proof of payment for reimbursement of costs of expert services performed upon request" document is automatically generated; it is necessary to print the form out directly from the internet browser. This document specifies the generated **variable symbol, which is to be used for the payment of the reimbursement of costs ofexpert activities performed upon request associated with the particular application**. For more detailed instructions please refer to the aforementioned website. Where the applicant does not have the possibility to complete the interactive form, they may obtain the document via SÚKL's mailroom (Annex 4).

Attachments to the application for expert activity:

- **Completed form "Proof of payment for reimbursement of costs of expert services performed upon request",** one counterpart (as per part 2 of the Guideline)
- **Proof of execution of payment for reimbursement of costs –** in case of a non-cash transfer, this shall mean a copy of the payment order endorsed by the bank or a copy of the statement of account (one counterpart); in case of cash payment made at the cash-desk, the SÚKL cashier shall endorse the payment directly in the document "Proof of payment for reimbursement of costs of expert services performed upon request".

5.2 Refund of cost reimbursement

Cost reimbursement shall be refunded as per the procedure outlined in SÚKL guideline UST-24 - Reimbursement of costs of expert activities conducted upon request – waivers and refunds.

5.3 Payment of additional cost reimbursement

Where the financial demands for the processing of the expert activity exceed the amount paid by the applicant, the applicant shall pay the additional costs using the variable symbol from a newly generated document "Proof of payment for reimbursement of costs of expert services performed upon request" in the amount covering the actual financial demands for the performance of the expert activity. The new variable symbol shall serve solely for the payment of the difference between the paid amount and the final amount; concurrently, the applicant shall contact the Accounting Department of the Institute which shall transfer the originally paid amount under the new variable symbol.

Pricelist of cost reimbursements

The reimbursement decree sets the following Pricelist of the amounts to be reimbursed for the expert activities conducted upon request and reimbursements of requested activities, which SÚKL provides pursuant to the below listed legal regulations:

- Act on Pharmaceuticals – parts A, B, C
- Act on Free Access to Information and Act on Libraries – part D
- Act on Budgetary Rules – part E
- Act on Medical Devices – part F

The charges are stipulated in full amounts.

The marketing authorisation holder pays costs of activities of the Institute related to the existing medicinal products marketing authorisations in the form of annual maintenance fees, which have to be paid for the following year by the end of each calendar year. Should the marketing authorisation holder fail to pay this amount within the stipulated deadline, he is reminded by the Institute to make the belated payment within 15 days as of the reminder delivery. The annual maintenance fee is not paid for the year when the marketing authorisation has been granted. Should the annual maintenance fee not be paid within the deadline set for belated payment, the marketing authorisation holder is obliged to pay the annual fee increased by 50%.
The payment of the increased amount is set by an interactive form dedicated to the payment of annual maintenance fee… - please tick the appropriate box..

In case of micro, small or medium enterprise the discount for parts A, B and C can be applied.
Pursuant to Section 3 of the reimbursement decree the applicant, who meets the requirements for inclusion in the category of micro, small and medium enterprise and does not carry out the activity related to the required task on the grounds of a contractual or any other similar relation on behalf of an entity, that does not meet the criteria of micro, small and medium enterprise, may ask for waiver of the payment of costs pursuant to Section 112 paragraph 3 letter b) of the Act on Pharmaceuticals together with submitting the documentation stated in Section 5 (3) of the reimbursement decree under letters a)-g).

The applicant shall reimburse the costs in compliance with the applicable legislation of the European Union amounting up to 50% of the amount stipulated in the pricelist for the required expert activity according to part A, B and C; to settle the actual amount within this scope the calculation formula stated in part C should be used. The State Institute for Drug Control (hereinafter referred to as “SUKL”) within the revision of UST-29 has amended the possibility for micro, small and medium enterprise to apply for discount on expert activities pursuant to the reimbursement decree ., on stipulating the amounts of reimbursement of costs of expert activities conducted within the scope of powers of the State Institute for Drug Control and the Institute for the State Control of Veterinary Biologicals and Medicaments and the process when the duty of annual maintenance fee payment pursuant to Section 112 of the Act on Pharmaceuticals, is not fulfilled.

With respect to the time demand of expert activities the costs for micro, small and medium enterprise are stipulated in full amount, i.e. 50% of the costs stipulated in the pricelist.

To evaluate the claim for part of the costs to be waived, the applicant shall submit the documentation stipulated in Section 5 (3) under letters of the reimbursement decree a)-g) related to the last accounting period pursuant to the reimbursement decree together with the application to carry out expert activity.
The Documents in points a) b) and c) of Section 5 (3) of the reimbursement decree are not required, when those have been already submitted by the applicant in the same year as part of a different application for expert activity.

a) data on average headcount
b) data on annual turnover of the applicant
c) applicant’s balance should the applicant be part of the consolidated body also consolidated balance; the balance possibly consolidated balance have to be verified by an auditor should it be stipulated by any other legal regulation.
d) Applicant’s declaration stating that the applicant is not in any business or other relation with any entity, that would not meet the stipulated criteria for inclusion in the category of micro, small and medium enterprise whereas business relation is considered a company where a different company or a group of companies own 25% and over of equity or voting rights, that do not meet the criteria of micro, small or medium enterprise,
e) Applicant’s declaration stating that the applicant does not perform any activity related to the required activity based on a contractual or other similar relation for the entity that does not meet the stipulated criteria for inclusion in the category micro, small and medium enterprise,
f) Trade licence, trade permit certificate, a copy of an entry in the Commercial Register, possibly articles of incorporation or status issued by a competent authority of the Czech Republic or other Member State,

which cannot date back more than three months at the time of submission, or any other document or licence authorising to carry out a business activity,

g) Applicant's declaration stating that all provided data and documents are up to date, complete and true.

GENERAL

Code	Category	Subcategory or specification	Amount of costs reimbursement
U-001	Annual maintenance fee	Conduct of expert activities in respect of the duration of marketing authorisation of a medicinal product with the exception of cases specified under codes U-002, U-003, U-004 and U-005	19 500.00 CZK
U-002	Annual maintenance fee	Conduct of expert activities in respect of the duration of marketing authorisation of a medicinal product where the Czech Republic is the Reference State	39 100.00 CZK
U-003	Annual maintenance fee	Conduct of expert activities in respect of the duration of marketing authorisation of a homeopathic product	3 000.00 CZK
U-004	Annual maintenance fee	Conduct of expert activities in respect of the duration of marketing authorisation of a medicinal product where the marketing authorisation holder is a micro-company	5 000.00 CZK
U-005	Annual maintenance fee	Conduct of expert activities in respect of the duration of marketing authorisation of a medicinal product where the marketing authorisation holder is a small company and homeopathic products are not involved	9 500.00 CZK
O-001	One-hour oral consultation or issuance of a written opinion concerning regulation upon request in a scope corresponding to a one-hour consultation (not related to a pending application).		3 100.00 CZK
O-002	One-hour oral consultation or issuance of a written opinion upon request in a scope corresponding to a one-hour consultation, addressing an issue relevant to the activities conducted by SUKL in the sphere of pharmaceuticals	E.g. a distinction to determine whether a clinical trial is concerned, a hospital exemption, a position on the use of pure alcohol (per one product), opinion on possible confusion of the name of a medicinal product requested outside the scope of a marketing authorisation procedure (max. 3 various names for a single product at one time), opinion on proposed advertising of a human medicinal product disseminated by channels other than radio and television	3 600.00 CZK

		broadcasting – preliminary assessment of the advertising materials.	
O-003	One-hour oral expert consultation or issuance of a written opinion upon request in a scope corresponding to a one-hour consultation (not related to a pending application)	E.g. an assessment of the design of the proposed clinical study, hospital exemption, preclinical testing, analytical method, statistical analysis, expert assessment of proposed texts (SPC, PIL).	12 500.00 CZK
O-004	Preparation and delivery of an expert lecture upon request of a business entity, associated with the content of SÚKL's operation (for the sphere of pharmaceuticals).	Dissemination of education (in the sphere of pharmaceuticals) at professional workshops and lectures	2 000.00 CZK/hour
O-005	Expert activities conducted upon request of a foreign company	Expert activities conducted at an hourly rate	2 000.00 CZK/hour
O-006	Application for processing of database system outputs generated based on the notifications filed by distributors and operators authorised to dispense medicinal products	Processing of specific outputs on distributed and dispensed medicinal products extracted from the respective databases applying expert viewpoints according to the required criteria and above the scope of usually and regularly published data	1 000.00 CZK/hour

MARKETING AUTHORISATION

Code	Category	Subcategory or specification	Amount of costs reimbursement
R-001	Application for a marketing authorisation of a medicinal product	•self-standing marketing authorisation supported by full experimental or bibliographic data (except self-standing marketing authorisation referred to under code R-002), fixed combination • marketing authorisation of a homeopathic product • marketing authorisation of a traditional herbal product • marketing authorisation of a similar biological product	250 000.00 CZK
R-002	Application for a marketing authorisation for a medicinal product	•generic marketing authorisation, marketing authorisation with the consent obtained from another holder and self-standing bibliographic marketing authorisation for electrolyte solutions of ATC group B05BB01, except complicated cases • hybrid marketing authorisation, i.e. generic marketing authorisation with data beyond the scope of essential similarity • marketing authorisation of a homeopathic product through a simplified procedure	200 000.00 CZK

R-003	Application for a marketing authorisation for a medicinal product	• marketing authorisation of a completely identical product under another name (duplicate)	70 000.00 CZK
R-004	Application for a marketing authorisation for a medicinal product	• another strength or pharmaceutical form (line extension)	100 000.00 CZK
R-007	Application for Type II variation to a marketing authorisation		70 000.00 CZK
R-008	Application for Type IA variation to a marketing authorisation, application for a change to the package labelling or package information leaflet unrelated to the summary of product characteristics and application for variation of a parallely imported medicinal product		6 000.00 CZK
R-009	Application for renewal of a marketing authorisation of a medicinal product	• all medicinal products except for homeopathic products	150 000.00 CZK
R-010	Application for renewal of a marketing authorisation of a medicinal product	• homeopathic products	35 000.00 CZK
R-011	Application for transfer of a marketing authorisation for a medicinal product		20 000.00 CZK
R-012	Application for approval with placing on the market of a batch of a medicinal product with labelling in a foreign-language		3 900.00 CZK
R-013	Application of a notified body for the issue of a position on a pharmaceutical forming an integral part of a medical device		70 000.00 CZK
R-014	Application for revocation of marketing authorisation	• without further requirements	None
R-015	Application for revocation of marketing authorisation	• with the requirement for phase-out sale	6 100.00 CZK
R-017	**MRP - RMS** MRP-RMS Application for initiation of a mutual recognition procedure (MRP) with the CR acting as a Reference Member State (RMS) (outgoing MRP application) Notices: This type of application shall be submitted after the national registration of the medicinal products concerned is completed (see R-001 to R-004)	• self-standing marketing authorisation supported by full experimental or bibliographic data (except self-standing marketing authorisation referred to under R-018), fixed combination • marketing authorisation of a traditional herbal product	250 000.00 CZK
R-17a	MRP-RMS R-017a If the application for marketing authorisation of a medicinal product, for which the commencement of the mutual recognition procedure for marketing authorisation has been applied for (with the Czech Republic being the reference Member State), has been submitted to SÚKL prior to June 5 2003 (as of when the amended Act No 79/1997 Coll., on Pharmaceuticals stipulates the obligation to comply with the	• self-standing marketing authorisation supported by full experimental or bibliographic data (except self-standing marketing authorisation referred to under R-018), fixed combination. • marketing authorisation of a traditional herbal product	350 000.00 CZK

		guidance issued by the European Commission and by the European Agency for the Evaluation of Medicinal Products), the amount shall be increased by approx. 50% due to the necessary verifications of compliance with all relevant guidelines in the submitted dossier.		

R-018		MRP-RMS Application for initiation of a mutual recognition procedure (MRP) with the CR acting as a Reference Member State (RMS) (outgoing MRP application). Notices: This type of application shall be submitted after the national registration of the medicinal products concerned is completed (see R-001 to R-004).	• generic marketing authorisation, marketing authorisation with the consent obtained from another holder and self-standing bibliographic marketing authorisation for electrolyte solutions of ATC group B05BB01, except complicated cases • hybrid marketing authorisation, i.e. generic marketing authorisation with data beyond the scope of essential similarity • marketing authorisation of a homeopathic product through a simplified procedure	200 000.00 CZK
R-18a		MRP-RMS R-018a - If the application for marketing authorisation of a medicinal product, for which the commencement of the mutual recognition procedure for marketing authorisation has been applied for (with the Czech Republic being the reference Member State), has been submitted to SÚKL prior to June 5 2003 (as of when the amended Act No 79/1997 Coll., on Pharmaceuticals stipulates the obligation to comply with the guidance issued by the European Commission and by the European Agency for the Evaluation of Medicinal Products), the amount shall be increased by approx. 50% due to the necessary verifications of compliance with all relevant guidelines in the submitted dossier.	• generic marketing authorisation, marketing authorisation with the consent obtained from another holder and self-standing bibliographic marketing authorisation for electrolyte solutions of ATC group B05BB01, except complicated cases • hybrid marketing authorisation, i.e. generic marketing authorisation with data beyond the scope of essential similarity marketing authorisation of a homeopathic product through a simplified procedure	300 000.00 CZK
R-020		MRP-RMS Application for initiation of a mutual recognition procedure (MRP) with the CR acting as a Reference Member State (RMS) (outgoing MRP application) Notices: This type of application shall be submitted after the national registration of the medicinal products concerned is completed (see R-001 to R-004)	• another strength or pharmaceutical form (line extension)	100 000.00 CZK

R-021		MRP-RMS Application for initiation of a mutual recognition procedure (MRP) with the CR acting as a Reference Member State (RMS) (outgoing MRP application) Notices: This type of application shall be submitted after the national registration of the medicinal products concerned is completed (see R-001 to R-004)	• marketing authorisation for an identical medicinal product with a different name (duplicate)	80 000.00 CZK
R-022		MRP-RMS Application for a repeated outgoing MRP with the CR acting as a Reference Member State (RMS)	Processing of this type of application includes both a decision on a variation or renewal as appropriate and ensuring the mutual recognition procedure for the application concerned.	100 000.00 CZK
R-023		MRP-RMS Application for variation type II within MRP where the CR is a Reference Member State	Processing of this type of application includes both a decision on a variation or renewal as appropriate and ensuring the mutual recognition procedure for the application concerned.	100 000.00 CZK
R-024		MRP-RMS Application for variation type IB within MRP where the CR is a Reference Member State	Processing of this type of application includes both a decision on a variation or renewal as appropriate and ensuring the mutual recognition procedure for the application concerned.	25 000.00 CZK
R-025		MRP-RMS Application for variation type IA and application for a change to the package labelling or package information leaflet unrelated to the summary of product characteristics within MRP where the CR is a Reference Member State	Processing of this type of application includes both a decision on a variation or renewal as appropriate and ensuring the mutual recognition procedure for the application concerned..	12 000.00 CZK
R-026		MRP-RMS Application for renewal of a marketing authorisation within MRP where the CR is a Reference Member State	Processing of this type of application includes both a decision on a variation or renewal as appropriate and ensuring the mutual recognition procedure for the application concerned.	200 000.00 CZK

R-027	**DECENTRALISED PROCEDURE / MRP - CMS**	DECENTRALIZED PROCEDURE/MRP-CMS Application for recognition of a marketing authorisation for a medicinal product granted by a competent authority of another Member State (incoming MRP) or for recognition of a marketing authorisation for a medicinal product	• self-standing application for MA supported by full experimental or bibliographic data (except for self-standing applications referred to under R-028) • marketing authorisation of a traditional herbal product • marketing authorisation of a similar biological product	110 000.00 CZK
R-028		DECENTRALIZED PROCEDURE/MRP-CMS Application for recognition of a marketing authorisation for a medicinal product granted by a competent authority of another Member State (incoming MRP)	• generic marketing authorisation, marketing authorisation with the consent obtained from another holder and self-standing bibliographic marketing authorisation for electrolyte solutions of ATC group B05BB01, except complicated cases	90 000.00 CZK

		or for recognition of a marketing authorisation for a medicinal product	• hybrid marketing authorisation, i.e. generic marketing authorisation with data beyond the scope of essential similarity • marketing authorisation of a homeopathic product through a simplified procedure	
R-030		DECENTRALIZED PROCEDURE/MRP-CMS Application for recognition of a marketing authorisation for a medicinal product granted by a competent authority of another Member State (incoming MRP) or for recognition of a marketing authorisation for a medicinal product	• another strength or pharmaceutical form	40 000.00 CZK
R-031		DECENTRALIZED PROCEDURE/MRP-CMS Application for recognition of a marketing authorisation for a medicinal product granted by a competent authority of another Member State (incoming MRP) or for recognition of a marketing authorisation for a medicinal product through a decentralized procedure	• marketing authorisation of a completely identical product under another name (duplicate)	30 000.00 CZK
R-032		DECENTRALIZED PROCEDURE / MRP-CMS Application for variation Type II of a marketing authorisation granted within MRP by a competent authority of another Member State		50 000.00 CZK
R-033		DECENTRALIZED PROCEDURE / MRP-CMS Application for variation Type IB to marketing authorisation granted within MRP by a competent authority of another Member State		10 000.00 CZK
R-034		DECENTRALIZED PROCEDURE / MRP-CMS Application for variation Type IA of a marketing authorisation and application for a change to the package labelling or package information leaflet unrelated to the summary of product characteristics granted within MRP by a competent authority of another Member State		4 000.00 CZK
R-035		DECENTRALIZED PROCEDURE / MRP-CMS Application for renewal of a marketing authorisation for a medicinal product granted within MRP by a competent authority of another Member State		80 000.00 CZK
R-036	Application for authorisation of parallel import of a medicinal product		•authorisation valid for one state of origin from which the product is to be imported	60 000.00 CZK

R-037		Application for authorisation of parallel import of a medicinal product	•authorisation for any other strength of the same medicinal product from the same state of origin	25 000.00 CZK
R-038		Application for authorisation of parallel import of a medicinal product	•authorisation valid for one state of origin from which the product is to be imported involving more complicated assessment of therapeutic comparability (e.g. a bio-equivalence study or independent stability study)	80 000.00 CZK
R-039		Application for renewal of authorisation of parallel import of a medicinal product		30 000.00 CZK
R-040		Application for Type IB variation to marketing authorisation		15 000.00 CZK
R-041	**DECENTRALISED PROCEDURE - RMS**	DECENTRALIZED PROCEDURE/RMS Application for commencement of a decentralized procedure of a marketing authorisation for a medicinal product with the CR as a reference member state	•self-standing application for MA supported by full experimental or bibliographic data (except for self-standing applications referred to under R-042), fixed combination •marketing authorisation of a traditional herbal product	390 000.00 CZK
R-042		DECENTRALIZED PROCEDURE/RMS Application for commencement of a decentralized procedure of a marketing authorisation for a medicinal product with the CR as a reference member state	• generic marketing authorisation, marketing authorisation with the consent obtained from another holder and self-standing bibliographic marketing authorisation for electrolyte solutions of ATC group B05BB01, except complicated cases • hybrid authorisation, i.e. generic authorisation with data beyond the scope of essential similarity • marketing authorisation of a homeopathic product through a simplified procedure	310 000.00 CZK
R-044		DECENTRALIZED PROCEDURE/RMS Application for commencement of a decentralized procedure of a marketing authorisation for a medicinal product with the CR as a reference member state	• another strength or pharmaceutical form (line extension)	170 000.00 CZK
R-045		DECENTRALIZED PROCEDURE/RMS Application for commencement of a decentralized procedure of a marketing authorisation for a medicinal product with the CR as a reference member state	•marketing authorisation for an identical medicinal product with a different name (duplicate)	120 000.00 CZK
R-046		Application for adoption of marketing authorisation from another Member State		None
R-047		Application for renewal of authorisation adopted from another Member State		None
R-048		Application for RMS (change from CMS to RMS)		100 000.00 CZK

R-049	Application for type II marketing authorisation variation in module 3 including a new a bio-equivalence study		90 000.00 CZK
R-050	Subsequent application of a notified body for the issuance of an opinion regarding a pharmaceutical which forms an integral part of a medical device, for which an opinion has already been issued previously (variation)	• change that could affect the quality, safety or beneficial effect of an active substance in a medical device, such as the change of the active substance manufacturer, change to the manufacturing of the active substance, change to the sterilization method, extension of the shelf life	15 000.00 CZK
R-051	Application for type II marketing authorisation variation in module 3 including a new a bio-equivalence study within MRP with the CR as a reference member state	Processing of this type of application includes both a decision on a variation or renewal as appropriate and ensuring the mutual recognition procedure for the application concerned.	120 000.00 CZK
R-052	Application for type II marketing authorisation variation in module 3 including a new a bio-equivalence study within a MRP granted for the medicinal product by a competent authority of another Member State		70 000.00 CZK

Formula for the calculation of the total amount of reimbursement of costs of marketing authorisation variations in grouped variations and worksharing procedure within one application:

Individual amounts of costs to be reimbursed for each marketing authorisation variation applied for in a single application shall be paid in the full amount for the first marketing authorisation number, while each additional marketing authorisation number included in the given application is subject to a 50% discount on the determined amount of costs to be reimbursed:

The amount of costs to be reimbursed (in CZK) = $(IA*m_{IA}) + (IB*m_{IB}) + (II*m_{II}) + (n-1)*0,5*((IA*m_{IA}) + (IB*m_{IB}) + (II*m_{II}))$

Where:
IA, IB, II = amount of reimbursement of costs associated with the respective type IA, IB or II marketing authorisation variation
m_{IA}, m_{IB}, m_{II} = number of marketing authorisation variations of the given type filed in one application
(n-1) = number of additional marketing authorisation numbers within one application.

INSPECTIONS

Code	Category	Subcategory or specification	Amount of costs reimbursement
I-001	Application for manufacturing authorisation for medicinal products/investigational medicinal products or variations to manufacturing authorisation with an inspection A variation to manufacturing authorisation consists of a change to the required type and scope of manufacture, incl. quality control tests which are to be performed or addresses of all manufacturing and quality control sites; where a reduction of the type and scope of manufacture or cancellation of a manufacturing site is concerned, the reimbursement shall be made as for a variation without inspection.	□ import from third countries releasing batches only manufacturing of other medicinal products manufacturing of investigational medicinal products for authorised manufacturing of medicinal products or vice versa (both sterile and non-sterile)	31 700.00 CZK
I-002	Application for manufacturing authorisation for medicinal products or variations to manufacturing authorisation with an inspection	non-sterile medicinal products – one pharmaceutical form and/or one manufacturing unit/line different in terms of manufacture at a single manufacturing site, including primary packaging, secondary packaging and releasing	56 200.00 CZK
I-003	Application for manufacturing authorisation for medicinal products or variations to manufacturing authorisation with an inspection	□ non-sterile medicinal products – increase for any other pharmaceutical form and/or manufacturing unit/line different in terms of manufacture cannot be used separately including primary packaging, secondary packaging and releasing	13 300.00 CZK
I-004	Application for manufacturing authorisation for medicinal products or variations to manufacturing authorisation with an inspection	□ sterile medicinal products – one pharmaceutical form and/or one manufacturing unit/line different in terms of manufacture at a single manufacturing site, including the primary packaging, secondary packaging and releasing	74 200.00 CZK
I-005	Application for manufacturing authorisation for medicinal products or variations to manufacturing authorisation with an inspection	□ sterile medicinal products - increase for any other pharmaceutical form and/or manufacturing unit/line different in terms of manufacture cannot be used separately, including primary packaging, secondary packaging and releasing	17 900.00 CZK
I-006	Application for manufacturing authorisation for medicinal products or variations to manufacturing authorisation with an inspection	□ an increase of the basic fee for the above-mentioned cases where biotechnological or technologically complex manufacture of biological preparations is concerned cannot be used separately	38 600.00 CZK
I-007	Application for manufacturing authorisation for medicinal products or variations to manufacturing authorisation with an inspection	□ a separately conducted primary packaging of non-sterile products - one pharmaceutical form and/or one manufacturing unit/line different in terms of manufacture at a single manufacturing site	33 100.00 CZK
I-008	Application for manufacturing authorisation for medicinal products or variations to manufacturing authorisation with an inspection	□ a separately conducted primary packaging of non-sterile products - increase for any other pharmaceutical form and/or manufacturing unit/line different in terms of manufacture	13 900.00 CZK

		cannot be used separately item I-001 shall not be applied	
I-009	Application for manufacturing authorisation for medicinal products or variations to manufacturing authorisation with an inspection	□ separately conducted secondary packaging at a single manufacturing site Item I-001 shall not be applied	30 600.00 CZK
I-010	Application for variation to manufacturing authorisation for medicinal products without inspection Variations to manufacturing authorisation concern changes to the following details: □ Name(s), surname, place of operation and identification number, if assigned, of the natural person who is applying for this authorisation; where this authorisation is applied for by a legal person, its company/business name, registered office, mailing address, and identification number, if assigned, □ name(s), surname, qualifications and expertise of qualified persons, □ name(s), surname, place of operation and identification number, if assigned, of the natural person who is contracted out to undertake parts of the manufacture or quality control, its company/business name, registered office, mailing address, and identification number, if assigned; In the case of a change to the company registration number (IČ) it is usually necessary to apply for a new authorisation; in the case of a contracted-out manufacture and quality control of medicinal products in third countries where the results of inspection by another authority cannot be recognised, the reimbursement shall be made as for an application for certification of GMP compliance with inspection at a foreign manufacturer's.	change to identification data change of or adding of a new qualified person change of or adding of a new contractor for manufacturing or quality inspection where the type and scope of manufacturing has been reduced or a manufacturing plant closed, the reimbursement is the same as in the case of variation without inspection joint payment for all variations	9 000.00 CZK
I-011	Application for distribution authorisation for medicinal products or variation to the distribution authorisation with inspection	□ with the inspection of a single warehouse • Variations to distribution authorisation concern a change to the requested type and scope of distribution or address of all sites where distribution is conducted.	25 300.00 CZK
I-012	Application for distribution authorisation for medicinal products or variation to the distribution authorisation with inspection	□ for any other warehouse within the scope of a single authorisation	13 300.00 CZK
I-013	Application for extension of distribution authorisation for the distribution of active substances and excipients, gases used in the delivery of healthcare services or for the distribution of blood and its components.	□ with the inspection of a single warehouse	25 300.00 CZK

I-014	Application for extension of distribution authorisation for the distribution of active substances and excipients, gases used in the delivery of healthcare services or for the distribution of blood and its components.	□ for any other warehouse within the scope of a single authorisation	13 300.00 CZK
I-015	Application for variation to the distribution authorisation for medicinal products without inspection	Extensions of distribution authorisation concern, in particular, the following data changes: □ Change of name, surname or place of operation and identification number, if assigned, of the natural person who is applying for this authorisation, where this authorisation is applied for by a legal person, its company/business name, registered office, mailing address and identification number, if assigned □ Change of name(s) a surname, qualifications and expertise of the qualified person. Where the identification number is changed, it is usually necessary to apply for a new authorisation.	7 400.00 CZK
I-016	Application for authorisation to engage in an activity as a control laboratory or variation to an authorisation to engage in an activity as a control laboratory with inspection Variations to an authorisation to engage in an activity as a control laboratory concern changes to quality control tests, which are to be conducted, or address of all quality control sites; in the event of abandoning certain authorised quality control tests or winding-up of a quality control site, compensation shall be made analogously to the variation without inspection.	□ partial testing single reimbursement for the inspection of manufactured and/or imported medicinal products and/or investigational medicinal products	31 400.00 CZK
I-017	Application for authorisation to engage in an activity as a control laboratory or variation to an authorisation to engage in an activity as a control laboratory with inspection	□ full-scope testing (physical, physico-chemical, and chemical testing of pharmaceuticals, or microbiological testing, biological testing) one payment for the inspection of manufactured and/or imported medicinal products and/or investigational medicinal products	40 000.00 CZK

I-018	Application for variation to an authorisation to engage in an activity as a control laboratory without inspection Variations to an authorisation to engage in an activity as a control laboratory concern changes to the following details: name(s), surname, place of operation and identification number, if assigned, of the natural person who is applying for this authorisation; where this authorisation is applied for by a legal person, its company/business name, registered office, mailing address, and identification number, if assigned; Where the identification number is changed, it is usually necessary to apply for a new authorisation; in the event of contracted-out controls of pharmaceuticals in third countries where the results of the inspection of another authority may not be recognised, compensation shall be made analogously to that for the application for Certificate of Compliance with GMP Requirements, with the conduct of an inspection at a foreign manufacturer's premises.	Inspection of investigational medicinal products in addition to an authorised inspection of medicinal products or, on the contrary, in the same scope. Inspection of import in addition to manufacturing and, on the contrary, specification in the same scope: change to the applicant's identification data new/changed or additional contractor for quality control joint payment for all variations	9 000.00 CZK
I-019	Application for the authorisation to manufacture transfusion products and starting materials for further production in blood centres or variation to the authorisation to manufacture transfusion products and starting materials for further production in blood centres with inspection A variation to an authorisation of the manufacture of transfusion products and raw materials for further production consists of a change to the required type and scope of manufacture, incl. quality control tests which are to be conducted, or addresses of all manufacturing and quality control sites; where a reduction of the type and scope of manufacture or cancellation of a manufacturing site is concerned, reimbursement shall be made as for a variation without inspection.	□ manufacture of transfusion products and starting materials for further production	40 000.00 CZK
I-020	Application for the authorisation to manufacture transfusion products and starting materials for further production in blood centres or variation to the authorisation to manufacture transfusion products and starting materials for further production in blood centres with inspection	□ blood or blood component collection only without further processing and/or whole blood production for autotransfusions	27 000.00 CZK
I-021	Application for the authorisation to manufacture transfusion products and starting materials for further production in blood centres or variation to the authorisation to manufacture transfusion products and starting materials for further production in blood	□ for any other manufacturing site within the scope of a single authorisation	7 400.00 CZK

	centres with inspection		
I-022	Application for variation to the authorisation to manufacture transfusion products and starting materials for further production in blood centres without inspection A variation to an authorisation of the manufacture of transfusion products and raw materials for further production consists of a change to the following data:		
	name(s), surname(s), place of business and company registration number (IČ), if allocated, of a natural person applying for this authorisation; if this authorisation is applied for by a legal person, the commercial company, or, if applicable, the name, registered office, mailing address and company registration number, if allocated, the name(s), surname(s), qualification and practical experience of qualified persons, the name(s), surname(s), place of business and company registration number (if allocated) of a natural person undertaking part of the manufacture or quality control on the basis of a contract; for a legal person the commercial company, or if applicable the name, registered office, mailing address and company registration number, if allocated; in the case of a change to the company registration number it is usually necessary to apply for a new authorisation; in the case of a contracted-out manufacture and quality control of pharmaceuticals in third countries where the results of inspection by another authority cannot be recognised, the reimbursement shall be made as for an application for certification of GMP compliance with inspection at a foreign manufacturer's.		9 000.00 CZK
I-023	Application for Certificate of Compliance with the Conditions of Good Manufacturing Practice in the manufacture of medicinal products, import from third countries, operation of control laboratory, and good distribution practice for the holders of relevant authorisations		1 700.00 CZK
I-024	Application for Certificate of Compliance with the Conditions of Good Manufacturing Practice for a specific medicinal product	Certificate for a Pharmaceutical Product in the WHO scheme.	2 200.00 CZK

I-025	Application for Certificate of Compliance with the Conditions of Good Manufacturing Practice in the manufacture of active substances	□ with the inspection of a single manufacturing unit/line	38 900.00 CZK
I-026		□ for any other manufacturing unit/line	13 300.00 CZK
I-027	Application for Certificate of Compliance with the conditions of Good Laboratory Practice or Good Clinical Practice	□ partial testing, studies using physical, chemical and biological testing systems with the exception of laboratory animals • survey of the clinical site, sponsor, and laboratories in order to assess compliance with the conditions of good clinical practice	31 400.00 CZK
I-028		□ studies using laboratory animals	38 900.00 CZK
I-029	Application for revocation of authorisation to engage in an activity		None
I-030	Application for Certificate of Compliance with GMP Requirements, with the conduct of the required type of inspection at a foreign manufacturer's ("Certificate") If the applications for GMP certificates requiring an inspection at a foreign manufacturer's premises are submitted as part of the marketing authorisation procedure for a medicinal product of the concerned manufacturer, they shall be handled regardless of the pending marketing authorisation procedure. Applications for marketing authorisation without adequate evidence of compliance with GMP requirements may not be successfully completed, and it is therefore pointless to submit at the same time or subsequently Type I-030 application to complete verification of the GMP compliance in parallel with the pending marketing authorisation.	Where it is possible to conduct several inspections within the scope of a single journey, several applicants may share the reimbursement of travel expenses and costs of stay.	Reimbursement as per the requested type of inspection incremented by 20% + reimbursement of travel expenses and costs of stay.
I-031	Application for the issue of certificate of compliance with the conditions of: □ good manufacturing practice in the manufacture of active substances □ good laboratory practice without on-site inspection		1 700.00 CZK
I-037	Application for registration of broker of medicinal products		3 300.00 CZK
I-038	Application for variation to the registration of broker of medicinal products		1 500.00 CZK
I-039	Application for Certificate of Compliance with the Conditions of Good Manufacturing Practice with inspection based on an application for marketing authorisation of a medicinal product by a company/sponsor of a clinical trial within a DCP	Compensation for travel costs and costs of stay may be shared by more than one applicant, provided that several inspections may be conducted during one trip. For inspections in the Czech Republic with participations from other member states, the calculation may include the costs of translation services	55 000.00 CZK + compensation of travel costs and costs of stay

I-040	Application for Certificate of Compliance with the Conditions of Good Manufacturing Practice with inspection based on an application for marketing authorisation of a medicinal product by a company/sponsor of a clinical trial within a DCP	For each additional site of inspection within one application + compensation of travel costs and costs of stay	30 000.00 CZK
I-041	Application for manufacturing authorisation for medicinal products or variations to manufacturing authorisation with an inspection Application for authorisation of a separate manufacturing warehouse of a medicinal product manufacturer	with the inspection of a single warehouse separate manufacturing warehouse	25 300.00 CZK
I-042	Application for manufacturing authorisation for medicinal products or variations to manufacturing authorisation with an inspection Application for authorisation of a separate warehouse of a manufacturer of medicinal products	for any other warehouse within one authorisation	13 300.00 CZK

PHARMACIES, VENDORS, LABORATORY ANALYSES, BATCH RELEASE

Code	Category	Subcategory or specification	Amount of costs reimbursement
L-001	Application for Certificate of Compliance with the conditions of Good Practice of Vendors of Selected Medicinal Products		7 400.00 CZK
L-002	Application for the issue of a binding opinion on material and technical facilities of a healthcare facility providing services of a pharmacy	□ for pharmacies or dispensaries of starting in new premises	22 100.00 CZK
L-003	Application for the issue of a binding opinion on material and technical facilities of a healthcare facility providing services of a pharmacy	□ for pharmacies or dispensaries of medical devices starting in premises of a formerly authorised pharmacy or medical devices dispensary □ starting a satellite dispensing unit for pharmaceuticals and medical devices modify the scope of pharmacy or dispensaries of medical devices creation of a specialized centre associated with a change to the pharmacy layout	7 400.00 CZK
L-004	Application for the issue of a binding opinion on material and technical facilities of a healthcare facility providing services of a pharmacy	□ modify the scope of activities of the pharmacy or dispensary of medical devices □ change of technical and material equipment of a pharmacy or dispensary of medical devices □ formal change to the data stated in the binding opinion	1 500.00 CZK
L-005	Laboratory analysis upon request		compensation as per the applied methods (part B of this Annex)

L-006	Application for Certificate of Compliance with the Conditions of Good Pharmacies Practice		22 100.00 CZK
L-007	Retesting a batch of a medicinal product prior to its release onto the market	□ with the submission of a certificate issued by an EU Member State	800.00 CZK
L-008	**Retesting a batch of a medicinal product prior to its release onto the market**	□ without the submission of a certificate issued by an EU Member State	800.00 CZK + compensation as per the applied methods (part B of this Annex)
L-009	Issue of a pharmacopoeia reference substance with a certificate upon request	□ per one bottle	800.00 CZK

CLINICAL TRIALS, THERAPEUTIC PROGRAMMES, DISTINCTIONS BETWEEN PHARMACEUTICALS AND OTHER PRODUCTS			
Code	**Category**	**Subcategory or specification**	**Amount of costs reimbursement**
K-001	Approval of a clinical trial on a medicinal product	• application for an approval of a clinical trial on a medicinal product Notices: The same amount of cost reimbursement applies also if an earlier approved/notified trial has not commenced within 12 months and major changes have been made to the original documentation.	67 300.00 CZK
K-002	Approval of a clinical trial on a medicinal product	• notification of a clinical trial on an authorised medicinal product (30 days) Notices: The same amount of cost reimbursement applies also if an earlier approved/notified trial has not commenced within 12 months and major changes have been made to the original documentation.	15 800.00 CZK
K-003	Approval of a clinical trial on a medicinal product	other notifications of clinical trials on medicinal products (60 days) Notices: The same amount of cost reimbursement applies also if an earlier approved/notified trial has not commenced within 12 months and major changes have been made to the original documentation.	33 900.00 CZK
K-004	Sponsor's notification of an amendment to the protocol Notices: Amendment to the Protocol requiring assessment due to a major change to the Protocol, which is likely to affect the safety of trial subjects or to alter the scientific hypothesis of the concerned clinical trial or if the change is significant for another reason. The costs shall be reimbursed in this amount also if the previously authorised/notified study has not commenced within 12 months and minor changes to the originally submitted documentation are made.		15 800.00 CZK

K-005	Application for the issuance of an opinion on the conditions of use of a medicinal product, method of its distribution, dispensing and monitoring, and its quality, safety and efficacy evaluations within a specific therapeutic programme		15 800.00 CZK For urgent opinions advance payment shall not be required.
K-006	Application for the issuance of a decision whether a product is a pharmaceutical (incl. a distinction between a medicinal product and an active substance), a medicinal product subject to marketing authorisation or any other product, or a homeopathic product, where applicable		6 900.00 CZK
K-007	Approval of a hospital exemption		90 000.00 CZK
K-008	Variation to a hospital exemption – changes to the manufacturing process, quality of the starting material		20 000.00 CZK
K-009	Variation to a hospital exemption – adding of a new facility that would administer the medicinal product subject to the hospital exemption, or increase of the maximum number of patients		2 500.00 CZK

B. Pricelist for the reimbursements of costs of laboratory analyses of pharmaceuticals and excipients conducted within the powers of the Institute

Item	Test	Service reimbursement
	PREPARATORY AND AUXILIARY ACTIVITIES	
1	Accepting of the sample for analysis and drafting of the plan of testing	500.00 CZK
2	Preparation for analysis	610.00 CZK
3	Validation of biological methods	1950.00 CZK
	PHYSICAL AND CHEMICAL TESTS	
4	Clarity and degree of opalescence of liquids – for each examined unit	40.00 CZK
5	Degree of coloration of liquids – for each examined unit	40.00 CZK
6	Potentiometric determination of pH	810.00 CZK
7	Density and relative density	1 010.00 CZK
8	Refractive index	810.00 CZK
9	Optical rotation	1 010.00 CZK
10	Viscosity – using a capillary viscosimeter	1 620.00 CZK
11	Viscosity - using a rotation viscosimeter	1 620.00 CZK
12	Viscosity – using a falling-ball viscosimeter	1 210.00 CZK
13	Distillation range	610.00 CZK
14	Boiling point	610.00 CZK
15	Determination of water by distillation	610.00 CZK
16	Melting point – capillary method	
16a	*For a labelled substance*	610.00 CZK
16b	*For an unlabelled substance*	1 210.00 CZK
17	Drop point	610.00 CZK
18	Freezing point	610.00 CZK
19	Potentiometric titrations	1 620.00 CZK
20	Absorption spectrophotometry infrared	2 830.00 CZK
21	Absorption spectrophotometry ultraviolet and visible	2 020.00 CZK
22	Thin-layer chromatography	
22a	*Qualitative determination – for each system*	1 130.00 CZK
22b	*Semi-quantitative determination – for each system*	1 740.00 CZK
23	Gas chromatography	
23a	*Simple determination*	5 660.00 CZK
23b	*Complex determination*	6 460.00 CZK
24	Liquid chromatography	
24a	*Simple determination*	5 040.00 CZK
24b	*Complex determination*	7 460.00 CZK
25	Liquid chromatography with mass detection	
26	Exclusion chromatography	
26a	*Exclusion chromatography of albumin*	10 040.00 CZK
26b	*Exclusion chromatography of immunoglobulins*	12 740.00 CZK
27	Electrophoresisof albumin and immunoglobulins	4 040.00 CZK
28	Conductivity	810.00 CZK
29	Ion and group identity testing	480.00 CZK
30	Smell	200.00 CZK
31	Ammonium (limit test)	480.00 CZK
32	Arsenic (limit test)	2 020.00 CZK
33	Calcium (limit test)	480.00 CZK
34	Chlorides (limit test)	480.00 CZK
35	Fluorides (limit test)	480.00 CZK
36	Magnesium (limit test)	480.00 CZK

37	Magnesium and alkaline-earth metals (limit test)	480.00 CZK
38	Heavy metals (limit test)	480.00 CZK
39	Iron (limit test)	480.00 CZK
40	Phosphates (limit test)	480.00 CZK
41	Potassium (limit test)	480.00 CZK
42	Sulphates (limit test)	480.00 CZK
43	Sulphated ash	2 420.00 CZK
44	Total ash	2 420.00 CZK
45	Free formaldehyde	
45a	*method A*	480.00 CZK
45b	*method B*	1 620.00 CZK
46	Identification and control of residua solvents	6 460.00 CZK
47	Residual ethylene oxide and dioxan	6 460.00 CZK
48	Acid value	1 210.00 CZK
49	Ester value	1 210.00 CZK
50	Hydroxyl value	1 210.00 CZK
51	Iodine value	1 210.00 CZK
52	Peroxide value	1 210.00 CZK
53	Saponification value	1 210.00 CZK
54	Determination of nitrogen by sulphuric acid digestion	4 040.00 CZK
55	Complexometric titrations	1 010.00 CZK
56	Water semi-microdetermination	2 020.00 CZK
57	Phenol in immunosera and vaccines	1 620.00 CZK
58	Oxidising substances	1 010.00 CZK
59	Total protein	1 620.00 CZK
60	Disintegration of tablets and capsules (without determination)	
60a	*Disintegration in water*	400.00 CZK
60b	*Disintegration is gastric juice*	1 010.00 CZK
60c	*Disintegration in duodenal juice*	1 820.00 CZK
61	Disintegration of suppositories and pessaries (without determination)	400.00 CZK
62	Dissolution test for solid pharmaceutical forms (without determination)	
62a	*Short-term dissolution*	1 010.00 CZK
62b	*Long-term dissolution*	4 850.00 CZK
63	Dissolution test for transdermal patches (without determination)	4 850.00 CZK
64	Uniformity of mass of single dose preparations – for each weighted amount	100.00 CZK
65	Friability of uncoated tablets	400.00 CZK
66	Resistance to crushing of tablets	200.00 CZK
67	Ethanol content	6 460.00 CZK
68	Test for methanol and 2-propanol	6 460.00 CZK
69	Test for extractable volume of parenteral preparations	200.00 CZK
70	Uniformity of mass of individual doses in multiple-dose packaging	100.00 CZK
71	Uniformity of dose units	100.00 CZK
72	Volumetric determination of substances	
72a	*Titration*	1 010.00 CZK
72b	*Retitration*	1 210.00 CZK
72c	*Titration in heterogeneous environment*	1 210.00 CZK
72d	*Titration in anhydrous environment (without isolation)*	1 210.00 CZK
73	Weighing of individual doses of medicines – for each weighted amount	100.00 CZK
74	Macroscopic description, appearance	200.00 CZK

	MICROBIOLOGICAL AND BIOLOGICAL TESTS	
75	Sterility	
75a	*Sterility – direct inoculation to substrates (products without antimicrobial effects)*	1 210.00 CZK
75b	*Sterility – direct inoculation to substrates (products with antimicrobial effects)*	1 410.00 CZK
75c	*Sterility – membrane filtration method*	2 210.00 CZK
75d	*Sterility of antibiotics - membrane filtration method*	2 210.00 CZK
76	Microbiological testing of non-sterile products (total count of live aerobes)	
76a	*Microbiological testing of non-sterile products – Category 2*	2 020.00 CZK
76b	*Microbiological testing of non-sterile products – Category 3B*	2 020.00 CZK
76c	*Microbiological testing of non-sterile products – Category 4A*	1 620.00 CZK
76d	*Microbiological testing of non-sterile products – Category 4B*	2 020.00 CZK
77	Mikrobiological quality of non-sterile products and substances for pharmaceutical use (TAMC, TYMC, tests for specified microorganisms)	
77a	non-aqueous preparations for oral use	2 020.00 CZK
77b	aqueous preparations for oral use	2 020.00 CZK
77c	rectal suppositories	2 020.00 CZK
77d	preparations for oral use, gingival, dermal, nasal, aural preparations	2 020.00 CZK
77e	preparations for vaginal use	2 020.00 CZK
77f	transdermal patches	2 020.00 CZK
77g	preparations for inhalation use	2 020.00 CZK
77h	pharmaceutical forms containing natural substances	2 020.00 CZK
77i	Substances for pharmaceutical use	2 020.00 CZK
78	Microbiological quality of herbal medicinal products for oral use	
78a	Herbal medicinal products - category A	2 020.00 CZK
78b	Herbal medicinal products - category B	2 020.00 CZK
78c	Herbal medicinal products - category C	2 020.00 CZK
79	Effectiveness of antimicrobial conservation substances	2 020.00 CZK
80	Bacterial endotoxins	1 620.00 CZK
81	anti-A a anti-B hemagglutinins – indirect method – (indirect Coombs test)	2 830.00 CZK
82	Immunochemical methods	
82a	*Methods in which a labelled antigen or a labelled antibody is used (ELISA)*	4 040.00 CZK
82b	*Immunoprecipitation methods – Ouchterlony*	4 040.00 CZK
82c	*Immunoprecipitation methods – Mancini*	2 420.00 CZK
83	Assay of tetanus vaccine adsorbed	70 000.00 CZK
84	Identity tests, tests of thermal stability and assay on tissue cultures	
84a	*Monovaccine*	5 460.00 CZK
84b	*Divaccine*	7 850.00 CZK
84c	*Trivaccine*	13 090.00 CZK
85	Cytotoxicity on tissue cultures	11 850.00 CZK

Note: Where the amount of reimbursement for an individual task or the sum of individual tasks according to the Pricelist is lower than CZK 1000, the amount of reimbursement to be paid shall be CZK 1000.Where the required method is not listed in the Pricelist, the amount of reimbursement of costs shall be defined on the basis of the formula provided in part C of the Pricelist. If consumer materials are necessary for the conduct of specific laboratory tests which are not normally available in the Institute, the price of the consumer materials shall be added to the amount of costs to be paid by the applicant. The amount of costs shall be, furthermore, incremented by laboratory analyses outsourced by the Institute in contract laboratories. In these cases the customer shall be informed prior to the conduct of the test and his/her approval shall be sought.

C. Calculation formula

Costs in CZK = x . b

where:
x = number of hours of work (each hour, even incomplete)

b = costs of 1 hour of work incl. payroll, costs of materials, services, and domestic travel costs, which are 1 500 **CZK** for the costs of the Institute.

D. Reimbursements for services associated with the provision of information and services of the specialised library

Item	Service description	Service reimbursement	Unit
1	**Copy services**		
1a	*A4 copy – one side*	2.00 CZK	piece
1b	*A4 copy – both sides*	4.00 CZK	piece
1c	*A3 copy – one side*	4.00 CZK	piece
1d	*A3 copy – both sides*	8.00 CZK	piece
1e	*Scanning - A4 format*	2.00 CZK	piece
2	**Procurement of technical data carriers**		
2a	*CD/DVD*	10.00 CZK	piece
3	**Sending of information to the applicant**		
3a	*Mailing services*	As per the current pricelist of Czech Post	
4	**Extraordinarily extensive information retrieval pursuant to the Act on Free Access to Information**		
4a	*Information retrieval*	272.00 CZK	Price for each (even if incomplete) hour
5	**Inter-library loan service (MVS)**		
5a	*Book unit loan from the library*	Free of charge	
5b	*Copy from the database*	20.00 CZK	Price for each set (even if incomplete) of 10 pages of the original
6	**Literature research, information from specialised databases**		
6a	*Conduct of research*	80.00 CZK	Price for each (even if incomplete) half-hour
6b	*Fee for output*	See items 1-3	

E. Reimbursement for other services

Item	Item name	Reimbursement of the service in CZK	
		per 1 hr. (even if incomplete)	**Per 1 day (8 hr. max.)**
1	**Assembly hall rental**	500.00 CZK	3500.00 CZK
2	**Equipment hire**		
2a	*Screen*	100.00 CZK	500.00 CZK
2b	*Overhead projector*	50.00 CZK	200.00 CZK
2c	*Laser pointer*	10.00 CZK	50.00 CZK
2d	*Flipchart (incl. paper)*	50.00 CZK	150.00 CZK
2e	*Writing aids for Flipchart*	20.00 CZK	60.00 CZK
2f	*PC use*	150.00 CZK	600.00 CZK
2g	*Audio technology use*	150.00 CZK	600.00 CZK
2h	*Data projector*	500.00 CZK	2 000.00 CZK
2f	*Technical background*	556.00 CZK	**3 448.00 CZK**

F. Medical devices

Code	Expert activity category (pursuant to Section 94, paragraph 1 of Act on Medical Devices)	Amount of cost reimbursement
110	Drafting of expert positions or opinions	1800 CZK/hour

The applicant shall be obliged to generate the document “Proof of payment for reimbursement of costs of expert services performed upon request” for the amount which corresponds to the anticipated time necessary for the conduct of the expert activity, using the following formula:

Reimbursement of costs in CZK = **h * s**,
where:

h = number of hours of work (each, even if incomplete, hour)

s = costs of 1 hour of work amounting to **1800 CZK**

The applicant shall be always obliged to generate the “Proof of payment for reimbursement of costs of expert services performed upon request” **at least** for the amount equal to the payment for:
- 4 hours where applications for expert position or opinion or opinion on clinical investigation are concerned;
- 4 hours where applications for assessment of whether the product is a medical device are concerned;
- 2 hours where applications for assessment of whether the medical device has been correctly classified are concerned.

Substitute form for obtaining details associated with the payment of an administrative fee

This form is intended for applicants who for whatever reasons themselves cannot retrieve the "Proof of Payment of Administrative Fee" directly from http://www.sukl.cz, section Administrative Fees and Reimbursements – Form. The completed form should be handed over or sent to SÚKL mail room. On the basis of these data SÚKL employees shall enter your request to the database in a standard manner and shall give you or send to you (as agreed) the "Proof of Payment of Administrative Fee" to be attached to your request.

Important notice:
This form does not fulfil the role of the "Proof of payment for reimbursement of costs of expert services performed upon request", which is to be submitted together with the application!!!

Explanatory notes:
For items with several options indicate your choice by checking the grey box (☒)
For items marked with *) applicants with registered office in the Czech Republic fill in their IČO, applicants with registered office abroad fill in the registration number under which the company has been incorporated in the country of its domicile, or the VAT number (DIČ).
Items marked with * are mandatory.

Applicant:

Business name*:
) ID:
Street*:
Building number*:
City*:
ZIP CODE*:
Country*:
E-mail:

Payer's bank account number *:

Contact/authorised person for communication with SÚKL on behalf of the applicant:

Title:
Name*:
Surname*:
Telephone*:
Fax:
E-mail:
The below listed details are to be completed only if the address of the contact/authorised person is different from that of the applicant:
Business name*:
) ID:
Street*:
Building number*:
City*:
ZIP CODE*:
Country*:

Instructions for handling regarding the generated document "Proof of payment for reimbursement of costs of expert services performed upon request" *:

a) document will be personally collected as agreed in advance with an employee of the SÚKL mail room: ☐

b) please send the document to the below listed contact: ☐

- *address:*
- *fax:*
- *e-mail:*

If your application pertains to marketing authorisation please complete the following details:

Name, pharmaceutical form, strength of the medicinal product *:	
Active substance*:	
Indication group*:	
Anticipated date of submission of the application *:	
Dossier in electronic format*:	Yes ☐ No ☐

Type of application – Payment of an administrative fees (part 1)

Substitute form for obtaining details associated with the reimbursement of costs for expert activities conducted upon request

This form is intended for applicants who for whatever reasons themselves cannot retrieve the "Proof of Payment of Administrative Fee" directly from http://www.sukl.cz, section Administrative Fees and Reimbursements – Form. The completed form should be handed over or sent to SÚKL mail room. On the basis of these data SÚKL employees shall enter your request to the database in a standard manner and shall give you or send to you (as agreed) the "Proof of Payment of Costs for Expert Activities Conducted upon Request" to be attached to your request.

Important notice:
This form does not fulfil the role of the "Proof of payment for reimbursement of costs of expert services performed upon request", which is to be submitted together with the application!!!

Explanatory notes:
For items with several options indicate your choice by checking the grey box (☒)
For items marked with *) applicants with registered office in the Czech Republic fill in their IČO, applicants with registered office abroad fill in the registration number under which the company has been incorporated in the country of its domicile, or the VAT number (DIČ).
Items marked with * are mandatory.

Applicant:

Business name*:
) ID:
Street*:
Building number*:
City*:
ZIP CODE*:
Country*:
E-mail:

Payer's bank account number *:

Contact/authorised person for communication with SÚKL on behalf of the applicant:

Title:
Name*:
Surname*:
Telephone*:
Fax:
E-mail:
The below listed details are to be completed only if the address of the contact/authorised person is different from that of the applicant:
Business name*:
) ID:
Street*:
Building number*:
City*:
ZIP CODE*:
Country*:

Instructions for handling regarding the generated document "Proof of payment for reimbursement of costs of expert services performed upon request" *:

a) document will be personally collected as agreed in advance with an employee of the SÚKL mail room: ☐

b) please send the document to the below listed contact: ☐

- *address:*
- *fax:*
- *e-mail:*

If your application pertains to marketing authorisation please complete the following details:

Name, pharmaceutical form, strength of the medicinal product *:	
Active substance*:	
Indication group*:	
Anticipated date of submission of the application *:	
Dossier in electronic format*:	Yes ☐ No ☐

For any other application please specify in more detail the content of the application in order to facilitate the identification of your payment *(e.g. inspection site, subject of the consultation, for codes O-001- 004 the employee who will handle the application or with whom the application has been discussed in advance, if applicable).*

Code of type of application – Pricelist of cost reimbursements (Annex 1):

Substitute form for obtaining of data for application associated with the payment for reimbursement of costs of expert activities performed upon request – medical devices

This form is intended for applicants who, for any reasons, cannot themselves generate the document "Proof of payment for reimbursement of costs of expert activities performed upon request" directly from http://www.sukl.cz, section Interactive form for application related to covering expenditures for expert activities conducted upon request and administrative fees. The completed form is to be submitted or sent to SÚKL mailroom. On the basis of these data, SÚKL employees shall enter your application into the database in a standard manner and shall provide you or send to you (as agreed) the document "Proof of payment for reimbursement of costs of expert services performed upon request"; this document is then to be submitted together with your application.

Important notice:
This form does not serve as the document of "Proof of execution of payment for reimbursement of costs of expert activities performed upon request" which is to be submitted with the application!!!

Explanatory notes:
In case of items where selection may be made, please check the grey field (☒)
In case of items marked with *), applicants established in the Czech Republic shall complete the Company Reg. No. (IČ), and applicants established abroad shall complete the registration number under which their company has been registered at the country of its registered office or the VAT Reg. No. (DIČ).
Items marked with * are mandatory.

Applicant:

Company name*:
) ID:
Street*:
Building no.*:
City/town*:
Postal Code*:
Country*:
E-mail:

Payer´s bank account number:

Contact/authorised person for acting on behalf of the applicant with SÚKL:

Title:
Name*:
Surname*:
Telephone*:
Fax:
E-mail:
Please complete the below specified data only if the address of the contact/authorised person is not identical with the address of the applicant:
Company name*:
) ID:
Street*:
Building number*:
City/town*:
Postal Code*:
Country*:

Generated document "Proof of payment for reimbursement of costs of expert services conducted upon request" *:

a) Will be personally collected upon previous agreement with a SÚKL mailroom employee: ☐

b) Is to be sent to the below specified contact: ☐

- *address:*
- *fax:*

Additional details *(such as basic data about the medical device, in case of a general application specification of the assessed area, or specification of the person with whom the application has been discussed in advance, where applicable)* ***:**

☐ ☐

Concerned application type code – see Pricelist of cost reimbursements (Annex 1):

State Institute for Drug Control
Šrobárova 48, 100 41 Prague 10
tel.: +420 272 185 111
fax: +420 271 732 377
e-mail: posta@sukl.cz
web: www.sukl.cz/

Application for administrative fee refund

Application Ref. no. / File ID:	
Type of application:	
Product name:	
Name of the applicant:	
Address of the applicant (street, P.O. BOX, City, ZIP Code, country)	
Contact person, address and telephone details of the contact person:	
Paid amount in CZK and payment date:	
Variable symbol of the payment*):	
Currency (of the below specified account for the refund of the payment):	
Applicant's bank (name and address):	
Applicant's account no./bank code:	
IBAN:	
SWIFT:	
National clearing code**):	
Rationale for the requested refund:	

*) Variable symbol specified on the document "Proof of payment for reimbursement of costs for expert services performed upon request"
**) Please complete only if known

_____ _____
Date Applicant's name and signature

3.1 Do not complete – for SÚKL's internal use

I agree/disagree with the refund of the amount of: CZK
Rationale – see the Decision on the refund of an administrative fee ref. no. .....dated.....

_____ _____
Date Name and signature of SÚKL section manager

Accountancy records: