

## UST-29 version 19 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 18 effective as of 1 June 2019

### Introduction

The guideline is being issued on the basis and 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 Guideline is for recommendation.

## 1 Payment of administrative fees

### 1.1 Procedure to be applied in the payment of administrative fees (except for administrative fees for applications referred to by the Act on Medical Devices)

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

Application type	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:		

<ul style="list-style-type: none"> <li>New active substance, new combination of active substances, new indication, new pharmaceutical form intended for new indications</li> </ul>	<b>20 000 CZK</b>	
<ul style="list-style-type: none"> <li>New pharmaceutical form without denomination for new indications, new strength</li> </ul>	<b>10 000 CZK</b>	
<ul style="list-style-type: none"> <li>Generic products or new pack sizes</li> </ul>	<b>8 000 CZK</b>	
<ul style="list-style-type: none"> <li>Others</li> </ul>	<b>10 000 CZK</b>	
<ul style="list-style-type: none"> <li>Foodstuffs for special medical purposes</li> </ul>	<b>10 000 CZK</b>	
<ul style="list-style-type: none"> <li>Medicinal products included in the registry of orphan medicinal products</li> </ul>	<b>0 CZK</b>	
<b>Application:</b>		
<ul style="list-style-type: none"> <li>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</li> </ul>	<b>20 000 CZK</b>	
<ul style="list-style-type: none"> <li>For variation to the decision on the established maximum price and amount and conditions of reimbursement in other cases</li> </ul>	<b>10 000 CZK</b>	
<b>Issuance of licence for the growing of medical cannabis</b>	<b>2 000 CZK</b>	
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	<b>50 CZK</b>	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	<b>40 CZK</b>	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	<b>15 CZK</b>	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 a public administration information system	<b>100 CZK</b>	For the first page and 50 CZK for each new page
Attestation of a counterpart, duplicate, copy, photocopy or excerpt from official files, from private files in official custody, from registers, from books, from records, from documentation, from documents or other written materials or images	<b>30 CZK</b>	For each page, incl. incomplete pages
Completion of authorised conversion of documents into electronic format	<b>30 CZK</b>	For each page, incl. incomplete pages of the converted document
Completion of authorised conversion of documents into paper-based format	<b>30 CZK</b>	For each page, incl. incomplete pages of the

		converted document
Acceptance of request for fine payment deferral or request for fine payment in instalments	<b>400 CZK</b>	

**Administrative fees shall be paid by bank transfer.**

**The variable symbol of the payment may be obtained by the applicant using interactive forms: available from <http://www.sukl.cz/modules/payment2/>**

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.

## **1.2 Procedure applicable to the payment of administrative fees for applications referred to by the Act on Medical Devices**

Pursuant to the provisions of the Act on Administrative Fees, the applicant shall be obliged to pay administrative fees for the following applications:

<b>Application type</b>	<b>Administrative fee amount</b>
Applications for notification or extension of notification of a serially manufactured medical device or accessories to a medical device placed on the market by the manufacturer or authorised representative	<b>500 CZK</b>
Applications for variation to notification of a serially manufactured medical device or accessories of a medical device placed on the market by the manufacturer or authorised representative	<b>50 CZK</b>
Notification of operation of a manufacturer of serially manufactured medicinal products	<b>2 500 CZK</b>
Notification of operation of a manufacturer of serially produced medicinal products	<b>2 500 CZK</b>
Notification of operation of an authorised representative pursuant to the Act on Medical Devices	<b>2 500 CZK</b>
Notification of operation of a medical device distributor	<b>2 500 CZK</b>
Notification of operation of a person servicing medical devices	<b>2 500 CZK</b>
Notification of operation of a medical device importer	<b>2 500 CZK</b>
Notification of operation of a sponsor of a medical device clinical investigation	<b>2 500 CZK</b>
Application for authorisation of a medical device clinical investigation	<b>500 CZK</b>
Application for the issue of a free sale certificate for a medical device	<b>500 CZK</b>

Applications shall be submitted and received via the Medical Device Registry (hereinafter referred to as “RZPRO”). In case of applications in respect of which the Act on Medical Devices sets forth an administrative fee for acceptance thereof, the RZPRO will generate the Payment Charge automatically.

## **1.3 Payment of administrative fees**

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 SÚKL 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:

<b>Name of the bank</b>	Česká národní banka
<b>Address of the bank</b>	Na Příkopě 28/3181 Praha 1 115 03

	Czech Republic
<b>Account number</b>	3711-623101
<b>Bank code</b>	0710
<b>IBAN</b>	CZ35 0710 0037 1100 0062 3101
<b>BIC (originally SWIFT)</b>	CNBACZPP
<b>Constant symbol</b>	1148
<b>Variable symbol</b>	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).

#### 1.4 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 (except for reimbursements of costs of activities conducted upon request referred to by the Act on Medical Devices)

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,B).

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 SÚKL 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:

<b>Name of the bank</b>	Česká národní banka
<b>Address of the bank</b>	Na Příkopě 28/3181 Praha 1 115 03 Czech Republic
<b>Account number</b>	35-623101
<b>Bank code</b>	0710
<b>IBAN</b>	CZ94 0710 0000 3500 0062 3101
<b>BIC (originally SWIFT)</b>	CNBACZPP
<b>Constant symbol</b>	0308
<b>Variable symbol</b>	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 C).

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:

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

<b>Constant symbol</b>	0308
<b>Variable symbol</b>	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 D). 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](mailto: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.

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

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

Pursuant to Section 94, paragraph 1 of Act on Medical Devices, SÚKL shall claim reimbursement of costs for expert activities performed upon request (expert opinions and reviews, clinical investigation authorisations, and changes to the conditions of a clinical investigation). This legal regulation allows SÚKL to charge adequate compensation of costs in advance. 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 E). 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:

<b>Name of the bank</b>	Česká národní banka
<b>Address of the bank</b>	Na Příkopě 28/3181 Praha 1 115 03 Czech Republic
<b>Account number</b>	10030 - 623101
<b>Bank code</b>	0710
<b>IBAN</b>	CZ40 0710 0100 3000 0062 3101
<b>BIC (originally SWIFT)</b>	CNBACZPP
<b>Constant symbol</b>	0308

<b>Variable symbol</b>	Generated by the process described below
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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 of expert 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
- Act on Free Access to Information and Act on Libraries – part C
- Act on Budgetary Rules – part D
- Act on Medical Devices – part E

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 "Yes" in the item "Payment after date".

In case of micro, small or medium enterprise the discount for parts A, B 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; to settle the actual amount within this scope the calculation formula stated in part C should be used.

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.

**A. Pricelist for the reimbursements of costs for the execution of expert activities upon request - Regulation No. 128/2019 Coll, <http://www.sukl.eu/modules/payment2/>**

**B. Pricelist for the reimbursements of costs of laboratory analyses of pharmaceuticals and excipients conducted within the powers of the Institute - Regulation No. 128/2019 Coll <http://www.sukl.eu/modules/payment2/>**

**C. 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	

**D. Reimbursement for other services**

Item	Item name	Reimbursement of the service in CZK ex. VAT*	
		per 1 hr. (even if incomplete)	Per 1 day (8 hr. max.)
<b>1</b>	<b>Assembly hall rental</b>	1000.00 CZK	6 500.00 CZK
<b>2</b>	<b>Kitchenette rental</b>	400.00 CZK	4 000.00 CZK

\*Basic VAT rate (21%) added to the total amount of rental.

**E. Medical devices**

Expert activities the application for which is generated through SÚKL's website

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.

**Expert activities the application for which is generated via RZPRO**

Code	Expert activity category (pursuant to Section 94, paragraph 2 of Act on Medical Devices)	Amount of cost reimbursement
210	Expert activities associated with the issue of authorisation of the conduct of a medical device clinical investigation	15 000 CZK
211	Expert activities associated with the issue of authorisation of changes to the conditions of a medical device clinical investigation	1 500 CZK

**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 IČ, applicants with registered office abroad fill in the code under which the applicant is registered in the SÚKL database (code will be communicated from the SÚKL accounting department).*

*Items marked with \* are mandatory.*

**Applicant:**

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

<b>Payer's bank account number *:</b>
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**Contact/authorised person for communication with SÚKL on behalf of the applicant:**

Title:
Name*:
Surname*:
Telephone*:
Fax:
E-mail:
<b>The below listed details are to be completed <u>only</u> if the address of the contact/authorised person is different from that of the applicant:</b>
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 <input type="checkbox"/> No <input type="checkbox"/>

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

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## 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 IČ, applicants with registered office abroad fill in the code under which the applicant is registered in the SÚKL database (code will be communicated from the SÚKL accounting department).*

*Items marked with \* are mandatory.*

### Applicant:

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

<b>Payer's bank account number *:</b>
---------------------------------------

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

Title:
Name*:
Surname*:
Telephone*:
Fax:
E-mail:
<b>The below listed details are to be completed <u>only if</u> the address of the contact/authorised person is different from that of the applicant:</b>
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 <input type="checkbox"/> No <input type="checkbox"/>

**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).

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

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## 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 code under which the applicant is registered in the SÚKL database (code will be communicated from the SÚKL accounting department). 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:
<b>Please complete the below specified data <u>only if</u> the address of the contact/authorised person is not identical with the address of the applicant:</b>
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:*
- *e-mail:*

**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):**



## Administrative Fee Refund Applications

Please fill in all the fields to clearly identify your application!

Application file no.		
Registration number *)		
Procedure no. **)		
Expert activity (for categories, see UST-29):		
Code (see UST-29):		
Name of product (in registration-related applications):		
Content of application		
Applicant's name:		
Applicant's address:	Street, PO Box:	Town, Postcode, State:
Contact:		
Contact person's address:		Phone, email:
Amount to refund (in CZK):		Date of payment:
Variable symbol ***)		Requested currency of refund:
Name of Applicant's bank:		Address:
Account no/bank code:		IBAN:
SWIFT:		National clearing code – if known:
Reason:		
Link to sources where claim can be verified:		

\*) Please state the registration number in application for the refund of the annual maintenance payment, or for the refund of reimbursements of costs of any proceedings relating to medicinal product already registered

\*\*) Number of procedure for mutual recognition procedures

\*\*\*) Variable symbol specified in the "Confirmation of Administrative Fee Payment" document

\_\_\_\_\_  
Date

\_\_\_\_\_  
Applicant's name and signature

### **Please do not fill in – for Institute's internal purposes:**

Administrative fee (AE) refund complies/does not comply with Section 7 of the Act on Administrative Fees:

- AF not contained in the pricelist was paid; AE paid by a person who is not its payer; excessive AF paid; or no application subject to AF as per the pricelist has not been received.

In light of the above, I consent/do not consent to the refund of: CZK

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name and signature of the operation's mandator

Decision was issued under file no..... on ....., to

a) refund the administrative fee in full

b) return a portion of the administrative fee of .....

c) refuse the application for the administrative fee refund

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name and signature, accountant of SÚKL