

UST- 36 version 2 - Administrative fees, reimbursement of costs for expert activities conducted upon request in compliance with Act No 296/2008 Coll., on Safeguarding the Quality and Safety of Human Tissues and Cells Intended for Use in Man

This guideline supersedes the guideline UST-36 version 1 effective as of 03 November 2009.

Introduction

The guideline is being issued in compliance with the provisions of Act No 296/2008 Coll., on Safeguarding the Quality and Safety of Human Tissues and Cells Intended for Use in Man and on Amendment to Related Acts (hereinafter referred to as the “Act on Human Tissues and Cells”) and of Act No 634/2004 Coll., on Administrative Fees, as amended (hereinafter referred to as the “Act on Administrative Fees”).

1. Payment of administrative fees

1.1 Procedure to be followed in the payment of administrative fees

With respect to the provisions of the Act on Administrative Fees, the applicant is obliged to pay administrative fees for the submission of an application.

For the submission of the following applications:	Administrative fee amount	Note
Application for:		
<ul style="list-style-type: none">• Authorisation to engage in the activities of a tissue centre or variation thereto	2,000 CZK	
<ul style="list-style-type: none">• Authorisation to engage in the activities of a donation centre or variation thereto	2,000 CZK	
<ul style="list-style-type: none">• Authorisation to engage in the activities of a diagnostic laboratory or variation thereto	2,000 CZK	

Administrative fees are to be paid by bank transfer, in exceptional cases cash at the cash desk. **The variable symbol for the payment** may be obtained by the applicant via the **interactive form**. For the purposes of payments of administrative fees and costs of expert activities conducted upon request, the form is available from <http://www.sukl.cz>, in the **Pricelist and Fees section**, section Administration fees – Manufacturing authorisation.

In the interactive form the applicant shall complete the required data relevant to the application. Once these are posted, the “Proof of administrative fee payment” is automatically generated which has to be printed directly from the internet browser. This form shows the generated variable symbol, which is to be used by the applicant in the payment of the administrative fee.

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

If the applicant does not have the option to generate the interactive form, it is possible to obtain the generated form via SÚKL mail room. In this case the applicant shall complete an alternative form (Annex 2 refers), and hand it over directly to a SÚKL employee or send it to the mail room via a public delivery service or by fax together with the request for generation of the relevant form. Based on the data provided by the applicant in the alternative form the employee of SÚKL mail room shall then generate the “Proof of administrative fee payment” form showing the relevant variable symbol (VS) and provide it to the applicant. Based on the allocated VS the applicant shall make the payment and shall submit the “Proof of administrative fee payment” together with the application.

SÚKL data 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 Česká republika
Account number	3711-623101
Bank sort code	0710
IBAN	CZ35 0710 0037 1100 0062 3101
BIC (originally SWIFT)	CNBACZPP
Constant symbol	1148
Variable symbol	Generated by the method described

Administrative fees not exceeding the amount of 5 thousand CZK may be paid using revenue stamps of the appropriate value attached to the generated "Proof of administrative fee payment" form which is part of the application. The revenue stamps are to be attached to the upper left part of the form. In order to secure a smooth hand-over of applications it is advisable to get the revenue stamps in advance. In exceptional cases, limited quantities of revenue stamps may be purchased at the SÚKL cash desk (hereinafter referred to as the "cash desk").

Administrative fees may be refunded only for reasons specified by the Act on Administrative Fees (Section 7).

Where any of the reasons for administrative fee refund specified by the Act arises and the applicant submits a request for refund, the Institute shall issue its decision concerning this request in compliance with Act No 337/1992 Coll., on the Administration of Taxes and Levies, as amended. It is recommended to use the "Request for Administrative Fee Refund" form (Annex 4) when requesting a refund.

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

1.2 Types and recommended payment methods applicable to additional payments of administrative fees

1.2.1 The applicant has paid a different (lower) administrative fee than the one established by the Pricelist (e.g. by mistake for another type of application)

Preferred method of making the additional payment:

- **bank transfer from the applicant's account** – the applicant shall again complete the interactive form specifying the correct activity to be paid for (as per item 1), shall obtain a new form with a variable symbol, under which the applicant shall make the payment of the outstanding amount; the applicant shall attach to two copies of the new "Proof of administrative fee payment" also the request for using the payment made under the old variable symbol for the new variable symbol (specifying both variable symbols and the amounts paid) and a request for the deletion of the old form, which will not be submitted to SÚKL.

Alternative method of making the additional payment:

- **Cash payment at the cash desk** – based on the submitted newly generated form (with a newly generated variable symbol), the applicant shall pay the outstanding amount at the cash desk and shall submit two copies of this new "Proof of administrative fee payment" endorsed by the cash desk together with the request for using the payment made under the old variable symbol for the new variable symbol (specifying both variable symbols and the amounts paid) and the request for the deletion of the old form which will not be submitted to SÚKL to the mail room.

1.2.2 The applicant has paid a lower administrative fee, e.g. due to a deduction of the bank's processing fees from the payment etc.

Preferred method of making the additional payment:

- **bank transfer from the applicant's account** – additional payment made by bank transfer using payment order for which the applicant shall use the same variable symbol as the one generated for the original payment

Alternative method of making the additional payment:

- **Cash payment at the cash desk** – the applicant shall pay the amount outstanding at the cash desk

2. Reimbursing costs for expert activities

2.1 Procedure to be followed when reimbursing the costs of activities conducted upon request

Pursuant to Section 27 of the Act on Tissues and Cells, SÚKL claims reimbursements of costs. These legal regulations allow SÚKL to claim the reimbursement of costs in advance. The reimbursement of costs is made **by bank transfer** prior to the submission of the application, exceptionally by cash payment of the amount established by the Pricelist (Annex 1, Part A refers) at the cash desk.

SÚKL data for bank transfers for 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	35-623101
Bank sort code	0710
IBAN	CZ94 0710 0000 3500 0062 3101
BIC (originally SWIFT)	CNBACZPP
Constant symbol	0308
Variable symbol	Generated by the method described

The form is automatically generated on the basis of the completed interactive form which is available from: www.sukl.cz, Pricelist and Fees section, the amounts of reimbursement of costs for expert activities associated with an application for authorisation to engage in an activity being provided in section "Inspections, distribution" under codes I-032 to I-036.

In the interactive form the applicant shall complete the required data. Once these are posted, the "Proof of payment of costs for expert activities conducted upon request" is automatically generated which has to be printed directly from the internet browser. This form shows the generated **costs for expert activities associated with the application in question**. For more detailed instructions please refer to the cited website.

If the applicant does not have the option to generate the interactive form, it is possible to obtain the generated form via SÚKL mail room. In this case the applicant shall complete an alternative form (Annex 3 refers), and hand it over directly to a SÚKL employee or send it to the mail room via a public delivery service or by fax together with the request for generation of the relevant form. Based on the data provided by the applicant in the alternative form the employee of SÚKL mail room shall then generate the "Proof of payment of costs for expert activities conducted upon request" form showing the relevant variable symbol (VS) and provide it to the applicant. Based on the allocated VS the applicant shall make the payment and shall submit the "Proof of payment of costs for expert activities conducted upon request" together with the application.

2.2 Types and recommended payment methods applicable to additional payments of costs

2.2.1 The applicant has reimbursed a different (lower) amount of costs than that established by the Pricelist (e.g. by mistake for another type of application)

Preferred method of making the additional payment:

- **bank transfer from the applicant's account** – the applicant shall again complete the interactive form specifying the correct activity to be paid for (as per item 2.1), shall obtain a new form with a variable symbol, under which the applicant shall pay the outstanding amount; the applicant shall attach to two copies of the new “Proof of payment of costs for expert activities conducted upon request” also the request for using the payment made under the old variable symbol for the new variable symbol (specifying both variable symbols and the amounts paid) and a request for the deletion of the old form, which will not be submitted to SÚKL.

Alternative method of making the additional payment:

- **Cash payment at the cash desk** – based on the submitted newly generated form (with a newly generated variable symbol), the applicant shall pay the outstanding amount at the cash desk and shall submit two copies of this new “Proof of payment of costs for expert activities conducted upon request” together with the request for using the payment made under the old variable symbol for the new variable symbol (specifying both variable symbols and the amounts paid) and the request for the deletion of the old form which will not be submitted to SÚKL.

2.2.2. The applicant has paid a lower reimbursement of costs, e.g. due to a deduction of the bank's processing fees from the payment etc.

Preferred method of making the additional payment:

- **bank transfer from the applicant's account** – additional payment made by bank transfer using payment order for which the applicant shall use the same variable symbol as the one generated for the original payment

Alternative method of making the additional payment:

- **Cash payment at the cash desk** – the applicant shall pay the outstanding amount at the cash desk specifying the original variable symbol.

2.3 Waivers and refunds of costs reimbursement

The procedure applicable to those cases where the Institute waives cost reimbursement or refunds parts thereof is specified in guideline SÚKL UST-24 - Waiver and refunds of reimbursement of costs for expert activities conducted upon request.

2.3 Annexes to the submitted application

- two copies* of the “**Proof of administrative fee payment**” (referred to in part 1. of the guideline);

- two copies* of the “**Proof of payment of costs for expert activities conducted upon request**” (referred to in part 2. of the guideline);

** Where the application is lodged via e-mail room at posta@sukl.cz, the applicant shall send only a single electronic copy of the Proof of administrative fee payment or Proof of payment of costs for expert activities conducted upon request signed with a certified electronic signature, specifying the variable symbol;*

- **proof of payment of costs and proof of payment of the administrative fee** (where the Act lists making the payment among particulars of the application) - in the case of a bank transfer it is a copy of the payment order endorsed by the bank or a copy of the bank

statement; in the case of a cash payment made at the cash desk the SÚKL cashier shall endorse the payment of the 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 administrative fee payment” form.

Once the payment is identified on SÚKL's bank account, the applicant will be sent one endorsed copy of the “Proof of payment of costs for expert activities conducted upon request” and one endorsed copy of the “Proof of administrative fee payment”.

It is advisable to make the bank transfer several days in advance of submitting the application, as the administrative fee and reimbursement of costs can be considered paid only when the amount is credited to the relevant SÚKL's bank account. If the application is submitted at the beginning of the year, it is not advisable to make the payment in the previous year due to payment reconciliation with accounting records. Applicants are advised that when making the administrative fee payment or reimbursing the costs by bank transfer it is necessary to make the payment in a manner ensuring that the **full** amount specified in SÚKL Pricelist is transferred to the SÚKL's bank account (the amount is specified on the automatically generated “Proof of payment of costs for expert activities conducted upon request” form with respect to the type of application or on the automatically generated “Proof of administrative fee payment” form) **and with the correct variable symbol**. For this purpose it is necessary to specify on the payment order the symbol “OUR”. Any fees associated with the transfer are paid by the applicant (please refer to the instructions below).

Important notice:

Should an **amount lower than that specified by SÚKL Pricelist** be transferred to SÚKL's bank account (e.g. because the bank has deducted processing fees from the amount), **the reimbursement of costs shall not be considered paid until additional payment of the outstanding amount as per the Pricelist is made** (possible procedures applicable to making the payment are specified under section 2.1.1 hereof).

Each payment has to be made separately as a single item of the payment order, so that a unique identification of the payment by variable symbol is practicable; **several partial payments hence cannot be made by a single lump sum payment**.

When making the payment, it is necessary to transfer the **concerned payment type to the correct account** (as explained in sections 1 and 2 hereof – Bank details).

Pricelist for cost reimbursements

• This Pricelist stipulates the reimbursements of costs for expert activities conducted upon request which are provided by SÚKL in compliance with the Act on Tissues and Cells.

A. Pricelist for the reimbursements of costs for expert activities conducted within the scope of powers of the Institute

EXPERT ACTIVITIES CONDUCTED UPON REQUEST			
Code	Category	Subcategory or specification	Cost reimbursement amount
I-032	Application for authorisation to engage in the activities of a tissue centre or variation to authorisation with inspection		63,000 CZK
I-033	Application for authorisation to engage in the activities of a tissue centre or for variation to authorisation with inspection – for any other operating site within the scope of a single authorisation, incl. donations taken by a donation centre without its own authorisation to engage in the activities pursuant to Section 10, paragraph 2 (b) of Act No 296/2008 Coll., or - for activities conducted with any other type of tissues and cells.		16,000 CZK
I-034	Application for authorisation to engage in the activities of a human tissue and cell donation centre or variation to authorisation with inspection		45,000 CZK
I-035	Application for authorisation to engage in the activities of a diagnostic laboratory or for variation to the authorisation to engage in the activities of a diagnostic laboratory with inspection		61,000 CZK
I-036	Application for authorisation to engage in the activities of a tissue centre or a donation centre or a diagnostic laboratory or for variation thereto without inspection		16,000 CZK

Alternative form for obtaining data for an application subjected to administrative fees

This form is intended for applicants who, for any reason, cannot themselves retrieve the “Proof of administrative fee payment” form directly from the internet address <http://www.sukl.cz>, section “Administrative fees and reimbursements – form”. Please hand over or send the completed form to SÚKL mail room. Using these data, the SÚKL staff will enter your application to the database in a standard manner and will give or send to you (as agreed) the “Proof of administrative fee payment” form to be submitted with the relevant application.

Important notice:

This form does not serve as the “Proof of administrative fee payment” submitted together with the application!!!

Explanations:

For items where it is possible to select from a list, please select by checking the appropriate grey field (x)

*For applicants based in the Czech Republic the item marked with *) shall be populated with the company registration number (IČ), for applicants based abroad with the registration number under which the company has been registered in its domicile country, or the VAT number (DIČ).*

*Completion of items marked with an asterisk * is mandatory.*

Applicant:

Company name*:
) ID:
Street*:
Building number*:
City*:
Postal code*:
Country*:

Payer’s bank account number *:

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

Title:
Name*:
Surname*:
Telephone*:
Fax:
E-mail:
The below specified boxes are to be completed <u>only if</u> the address of the contact/authorised person is not identical to that of the applicant:
Company name*:
) ID:
Street*:
Building number*:
City*:
Postal code*:
Country*:

The generated “Proof of administrative fee payment” form*:

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

b) is to be sent to the below provided contact details:

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

If the application concerns marketing authorisation, please complete the following details:

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

Type of application – please refer to the Administrative Fee Pricelist (Part 1):

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Alternative form for obtaining data for an application associated with reimbursement of costs for expert activities conducted upon request

This form is intended for applicants who, for any reason, cannot themselves retrieve the “Proof of payment of costs for expert activities conducted upon request” form directly from the internet address <http://www.sukl.cz>, section “Administrative fees and reimbursements – form”. Please hand over or send the completed form to SÚKL mail room. Using these data, the SÚKL staff will enter your application to the database in a standard manner and will give or send to you (as agreed) the “Proof of payment of costs for expert activities conducted upon request” to be submitted with the relevant application.

Important notice:

This form does not serve as the “Proof of payment of costs for expert activities conducted upon request” submitted together with the application!!!

Explanations:

For items where it is possible to select from a list, please select by checking the appropriate grey field (x)

*For applicants based in the Czech Republic the item marked with *) shall be populated with the company registration number (IČ), for applicants based abroad with the registration number under which the company has been registered in its domicile country, or the VAT number (DIČ).*

*Completion of items marked with an asterisk * is mandatory.*

Applicant:

Company name*:
) ID:
Street*:
Building number*:
City*:
Postal code*:
Country*:

Payer’s bank account number*:

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

Title:
Name*:
Surname*:
Telephone*:
Fax:
E-mail:
The below specified boxes are to be completed <u>only if</u> the address of the contact/authorised person is not identical to that of the applicant:
Company name*:
) ID:
Street*:
Building number*:
City*:
Postal code*:
Country*:

The generated “Proof of payment of costs for expert activities conducted upon request” form*:

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

b) is to be sent to the below provided contact details:

• *address:*

• *fax:*

• *e-mail:*

If the application concerns marketing authorisation, please complete the following details:

Name, pharmaceutical form, strength of the medicinal product*:

Active substance*:

Indication group*:

Expected application submission date*:

Documentation in electronic format*: Yes No

For any other applications please provide a more detailed specification of the application in order to facilitate the identification of the payment (*e.g. site of inspection; subject of consultation; for codes O-001- 004 the employee who will process the application or with who has been notified thereof in advance, etc.*)

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Code of the relevant application type – please refer to the Cost Reimbursement Pricelist (Annex 1):

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Application for administrative fee refund

Application ref. no./file no.:	
Application type:	
Product name:	
Name of applicant:	
Address of the applicant (street, P.O. Box, city, Postal Code, country):	
Contact person, address and telephone of the contact person:	
Amount paid in CZK and date of payment:	
Variable symbol of the payment*):	
Currency (of the below specified account for payment refund):	
Applicant's bank (name and address):	
Applicant's account number/bank sort code:	
IBAN:	
SWIFT**):	
National clearing code**):	
Rationale of request for refund:	

*) the variable symbol specified on the "Proof of administrative fee payment" form

**) specify only if known

Date _____

Name and signature of the applicant

Do not complete –for SÚKL internal purposes only

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

- administrative fee which is not in the Pricelist has been paid or administrative fee has been paid by person who is not obliged to pay it or excess payment of the administrative fee has been made

With regard to this I approve/decline the refund of the amount of: CZK

Date _____

Name and signature of expert section manager

Decision file no..... issued on....., ruling that:

- a) the administrative fee is to be fully refunded;
- b) the administrative fee is to be refunded in the amount of
- c) the request for administrative fee refund is declined.

Date _____

Name and signature of SÚKL head accountant