

UST-36 version 6

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 and on Amendment to Related Acts.

This guideline supersedes the guideline UST-36 version -4 effective as of 22.02.2019

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”), Annex to Decree No 28/2019 Coll., establishing the list of professional activities and the amount of the payment of expenses for professional activities performed by the State Institute for Drug Control according to the requirement of the Human Tissue and Cells Act 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
Application for:	
• Authorisation to engage in the activities of a tissue centre or variation thereto S-015	2,000 CZK
• Authorisation to engage in the activities of a donation centre or variation thereto S-016	2,000 CZK
• Authorisation to engage in the activities of a diagnostic laboratory or variation thereto S-017	2,000 CZK
• Authorisation to engage in the activities of a distribution of human tissues and cells S-020	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 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. 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 human 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-038.

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.

3. Annexes to the submitted application

- copy of the “**Proof of administrative fee payment**” (referred to in part 1. of the guideline);
- copy 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 2.2 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).

Annex 1 - Pricelist for cost reimbursements

Annex 2 - Substitute form for obtaining details associated with the payment of an administrative fee
Substitute form for obtaining details associated with the reimbursement of costs for expert activities conducted upon request – UST-29 Annex 3

Administrative Fee Refund Applications – UST-29 Annex 5

Pricelist for Reimbursement of Costs

In compliance with [Section 29](#) and implementing [Section 27, paragraph 1 of Act No 296/2008 Coll.](#), on Safeguarding the Quality and Safety of Human Tissues and Cells Intended for Use in Man and on Amendments to Related Acts (Act on Human Tissues and Cells), as amended by Act No [77/2012 Coll.](#) and Act No [136/2017 Coll.](#), the Ministry of Health establishes:

List of expert activities conducted by the State Institute for Drug Control and amounts of reimbursements of costs thereof, as set forth by Annex to Decree No 28/2019 Coll.

Code	Expert activity	Amount of reimbursement of costs
LTB-I-032	Assessment of application for authorisation to engage in the activities of a tissue centre	64,800 CZK
LTB-I-032A	Assessment of application for variation to authorisation to engage in the activities of a tissue centre with on-site inspection at the premises of the foreseen operation	22,500 CZK
LTB-I-033	Assessment of application for authorisation to engage in the activities of a tissue centre or variation thereto with on-site inspection at the premises of the foreseen operation – for any additional operation site within the scope of a single authorisation	16,200 CZK
LTB-I-034	Assessment of application for authorisation to engage in the activities of a donation centre	38,700 CZK
LTB-I-034A	Assessment of application for variation to authorisation to engage in the activities of a donation centre with on-site inspection at the premises of the foreseen operation	14,400 CZK
LTB-I-035	Assessment of application for authorisation to engage in the activities of a diagnostic laboratory	59,400 CZK
LTB-I-035A	Assessment of application for variation to authorisation to engage in the activities of a diagnostic laboratory with on-site inspection at the premises of the foreseen operation	20,700 CZK
LTB-I-035B	Assessment of application for authorisation to engage in the activities of a diagnostic laboratory or variation thereto with on-site inspection at the premises of the foreseen operation – for any additional operation site within the scope of a single authorisation	15,300 CZK
LTB-I-036	Assessment of application for variation to authorisation to engage in the activities of a tissue centre, donation centre, diagnostic laboratory or distribution of human tissues and cells without on-site inspection at the premises of the operation	9,000 CZK

LTB-I-037	Assessment of application for authorisation to distribute human tissues and cells	26,100 CZK
LTB-I-037A	Assessment of application for variation to authorisation to distribute human tissues and cells with on-site inspection at the premises of the foreseen operation	12,600 CZK
LTB-I-037B	Assessment of application for authorisation to distribute human tissues and cells or variation thereto with on-site inspection at the premises of the foreseen operation – for any additional operation site within the scope of a single authorisation	10,800 CZK
LTB-I-038	Assessment of application for authorisation to engage in the activities of an importing tissue centre or variation thereto – on-site inspection at the premises of the third-country supplier's operation	Reimbursement as per similar activity coded I-032, I-032A, or I-033 incremented by 20 % and compensation of travel costs and subsistence.

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:

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 <u>only if</u> 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:*

Type of application – please refer to the Administrative Fee Pricelist (Part 1.1):