

UST-29 version 22 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 21 effective as of 14. 4. 2022

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”), of Act No 89/2021 Coll., on Medical Devices and on Amendment to Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended (hereinafter referred to as the “Act on Medical Devices”), and Act No 268/2014 Coll., on in Vitro Diagnostic Medical Devices, as amended (hereinafter referred to as the “Act on in Vitro Medical Devices”), and Act No 167/1998 Coll., on Dependency-Producing Substances and on Amendments to Some Other Acts, as amended (hereinafter referred to as the “Act on Dependency-Producing Substances”).

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:		

Application type	Administrative fee amount	Remark
<ul style="list-style-type: none"> For distribution authorisation for medicinal products or variation thereto 	2 000 CZK	
<ul style="list-style-type: none"> 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"> New active substance, new combination of active substances, new indication, new pharmaceutical form intended for new indications 	20 000 CZK	
<ul style="list-style-type: none"> New pharmaceutical form without denomination for new indications, new strength 	10 000 CZK	
<ul style="list-style-type: none"> Generic products or new pack sizes 	8 000 CZK	
<ul style="list-style-type: none"> Others 	10 000 CZK	
<ul style="list-style-type: none"> Foodstuffs for special medical purposes 	10 000 CZK	
<ul style="list-style-type: none"> Medicinal products included in the registry of orphan medicinal products 	0 CZK	
Application:		
<ul style="list-style-type: none"> For determination of or variation to the maximum price or amount and conditions of reimbursement of a medicinal product/food for special medical purposes 	2 000 CZK	
<ul style="list-style-type: none"> For determination of or variation to the maximum price or amount and conditions of reimbursement – medicinal products included in the registry of orphan medicinal products 	0 CZK	
Application:		
<ul style="list-style-type: none"> For granting of a licence for the growing of medical cannabis 	2 000 CZK	
<ul style="list-style-type: none"> For renewal of a licence for the growing of medical cannabis 	2 000 CZK	
<ul style="list-style-type: none"> For variation to a licence for the growing of medical cannabis 	2 000 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 a public administration information system	100 CZK	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	30 CZK	For each page, incl.

Application type	Administrative fee amount	Remark
books, from records, from documentation, from documents or other written materials or images		incomplete pages
Completion of authorised conversion of documents into electronic format	30 CZK	For each page, incl. incomplete pages of the converted document
Completion of authorised conversion of documents into paper-based format	30 CZK	For each page, incl. incomplete pages of the converted document
Acceptance of request for fine payment deferral or request for fine payment in instalments	400 CZK	

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 and by the Act on in Vitro 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:

Via the Medical Device Registry (hereinafter referred to as "RZPRO") Application type	Administrative fee amount
Applications for notification or extension of notification of a serially manufactured in vitro diagnostic medical device or accessories to an in vitro diagnostic medical device placed on the market by the manufacturer or authorised representative	500 CZK
Notification of operation of a manufacturer of serially manufactured in vitro diagnostic medical devices	3 000 CZK
Notification of operation of an authorised representative pursuant to the Act on in Vitro Diagnostic Medical Devices	3 000 CZK
Notification of operation of a distributor of in vitro diagnostic medical devices	3 000 CZK
Notification of operation of a person servicing in vitro diagnostic medical devices	3 000 CZK
Notification of operation of an importer of in vitro diagnostic medical devices	3 000 CZK
Application for the issue of Certificate of Free Sale for an in vitro diagnostic medical device	1 000 CZK
Notification of the commencement of operation of custom-made medical devices manufacturer	3 000 CZK
Notification of the commencement of operation of medical device distributor	3 000 CZK
Notification of the commencement of operation of a person servicing medical devices	3 000 CZK
Application for renewal of invalidated data of a notified person in the Medical Device Information System	1 500 CZK

Via the Medical Device Registry (hereinafter referred to as “RZPRO”) Application type	Administrative fee amount
Application for authorisation of a medical device clinical investigation	1 000 CZK
Application for the issue of Certificate of Free Sale for a medical device	1 000 CZK

Applications shall be submitted and received via RZPRO. In case of applications in respect of which the Act on Medical Devices and the Act on in Vitro Diagnostic Medical Devices set forth an administrative fee for acceptance thereof, the RZPRO will generate the Payment Charge automatically.

Via web applications Application type	Administrative fee amount
Verification of data pursuant to Art. 31(1) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (hereinafter referred to as the “Medical Device Regulation”) and allocation of single registration number referred to under Art. 31(2) of the Medical Device Regulation to the manufacturer, authorised representative or importer	3 000 CZK

Applications for the allocation of single registration number (SRN) are processed in the European database of medical devices (EUDAMED). The fee for data verification and SRN allocation shall be collected only as of the complete roll-out of fully functional EUDAMED. The roll-out of the Actors module in the EUDAMED database took place on 1 December 2020 for the purposes of voluntary registration. According to the opinion of the European Commission, the use of the Actors module is not enforceable prior to the roll-out of fully functional EUDAMED.

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:

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).

1.4 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 and the Act on Dependency-Producing Substances)

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, G).

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:

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 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:

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

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 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:

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 and pursuant to the Act on in Vitro Diagnostic Medical Devices

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

Pursuant to Section 66(2) of the Act on Medical Devices, SÚKL shall claim reimbursement of costs for expert activities performed upon request (expert opinions and reviews, provision of expert consultations, preparation and conduct of educational activities, clinical investigation authorisations, authorisations of variations to the conditions of clinical investigations, assessment of another clinical investigation and variations to the conditions thereof as per Art. 82 of the Medical Device Regulation, assessment of clinical investigations as per Art. 74 of the Medical Device Regulation); reimbursement of costs shall be also claimed for expert activities conducted upon request pursuant to Section 94(2) of the Act on in Vitro Diagnostic Medical Devices (expert opinions and reviews, provision of expert consultations, preparation and conduct of educational activities). These legal regulations allow 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, parts E, 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 Czech Republic
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
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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.

6. Payment of reimbursement of costs for expert activities pursuant to the Act on Dependency-Producing Substances

6.1 Procedure to be employed in making payments for the reimbursement of costs of activities performed upon request

Pursuant to Section 24f(1) of the Act on Dependency-Producing Substances, the Institute collects reimbursement of costs of expert activities performed upon request. Expert activities shall mean those activities that are conducted in association with procedures concerning applications referred to under Section 24b(2) (granting of licence to grow medical cannabis plants), Section 24c(3) (renewals of granted licences), and Section 24c(5) (changes to data specified in the licence). The Act on Dependency-Producing Substances stipulates that the person on whose request the expert activities are to be conducted, shall be obliged to make an advance payment to the Institute as the reimbursement of costs. The amount of the advance payment is stipulated by Decree No 53/2022 Coll., on the determination of the amount of reimbursement of costs of expert activities conducted by the State Institute for Drug Control pursuant to the Act on Dependency-Producing Substances.

The applicant is obliged to generate a proof of payment for the amount stipulated by the Pricelist (see Annex 1, Part H) using an interactive form.

The applicant is obliged to make the advance payment for reimbursement of costs via a bank transfer, using the generated variable symbol, prior to the submission of the application. The amount of the payment is specified in Czech crowns. When making the payment, it is therefore necessary to instruct the bank to transfer the full required amount of the payment to SÚKL’s account and to charge any bank fees to the payer.

SÚKL's details for bank transfers of reimbursements of costs of expert activities:

Bank name	Česká národní banka
Bank address	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 process described below

The proof of payment is automatically generated on the basis of a completed interactive form which is available from the following website: <http://www.sukl.cz>, under section Pricelist and fees.

The applicant shall complete the required data into the interactive form. Following submission, document "Proof of payment for reimbursement of costs of expert services performed upon request" is automatically generated, which has to be printed directly from the web browser. The document shows the generated **variable symbol to be used for the payment of the reimbursement of costs of expert activities associated with the application in question**. Detailed guidance is available from the aforementioned website.

Attachments to the application for expert activity:

- Completed form **"Proof of payment for reimbursement of costs of expert services performed upon request"** (one copy, as required by section 2 hereof)
- **Proof of payment for reimbursement of costs** – in case of cashless transfer, this shall mean a copy of the payment order or of account statement endorsed by the bank (one copy); in case of cash payments made at the cash-desk, SÚKL's cashier shall endorse the payment of the reimbursement of costs directly in the "Proof of payment for reimbursement of costs of expert services performed upon request" document.
- Completed form **"Proof of payment of administrative fee"** (one copy, as required by section 1 hereof)

6.2 Cost reimbursement refunds

Cost reimbursement refunds shall follow the procedure outlined in SÚKL Guideline UST-24 Waiver and refunds of reimbursement of costs for expert activities conducted upon request.

6.3 Payment of additional cost reimbursement

Payment of additional reimbursement in case the financial costs of the processing of the expert activities are higher than the amount paid by the applicant shall be made by the applicant under the variable symbol provided on a newly generated "Proof of payment for reimbursement of costs of expert services performed upon request" document. The applicant shall be informed about the amount of additional cost reimbursement in an Invitation to pay additional cost reimbursement. Using the new variable symbol, the applicant shall only pay this additional charge and, at the same time, shall contact SÚKL's Accounting Unit, which shall transfer the originally made advance payment to the new variable symbol.

Annexes

Annex 1: Pricelist of cost reimbursements

Annex 2: Substitute form for obtaining details associated with the payment of an administrative fee

Annex 3: Substitute form for obtaining details associated with the reimbursement of costs for expert activities conducted upon request

Annex 4: Substitute form for obtaining of data for application associated with the payment for reimbursement of costs of expert activities performed upon request – medical devices

Annex 5: Administrative Fee Refund Applications