UST- 29 version 7
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 6 effective as of 22 December 2009.

Introduction

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

The State Institute for Drug Control (hereinafter referred to as "SÚKL") has, within the scope of a revision of guideline UST-29, amended the possibility of discount for micro, small and medium enterprise for items in the Pricelist of reimbursements of costs of expert activities and annual maintenance fees pursuant to Decree No 427/2008 Coll., stipulating the amounts of reimbursement of costs of expert activities conducted within the scope of powers of the State Institute for Drug Control and the Institute for the State Control of Veterinary Biologicals and Medicaments and the process when the duty of annual maintenance fee payment pursuant to Act No. 112 Decree No 378/2007 Coll., on Pharmaceuticals, is not fulfilled.

1 Payment of administrative fees

1.1 Procedure to be applied in the payment of administrative fees

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

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

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

Administrative fees shall be paid by bank transfer.

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

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

In the interactive form, the applicant shall complete the required data relevant to the application. Once these are posted (from the web) to the administrative authority, the "Proof of payment of Administrative Fee" will be automatically generated for the applicant. The document has to be printed directly from the web browser. The document contains the variable symbol of the payment allocated to the application by the SÚKL identification system.

The applicant shall use the allocated variable symbol for the identification of the payment by bank transfer. The amount is stated in Czech Crowns. When making the payment it is necessary to inform the bank that the payment must be transferred to the SUKL account in the required currency and full amount and any costs of bank transfer/service charges shall be borne by the payer.

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

SÚKL details for bank transfers of administrative fee payments:

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

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

1.2 Administrative fee refunds

Paid administrative fees may be refunded only for reasons stipulated by the Act on Administrative Fees (section 7). If any of the statutory reasons for administrative fee refund arises, and the applicant files a request for refund, SÚKL shall decide about this request in compliance with Act No 337/1992 Coll., on the Administration of Taxes and Levies, as amended.
The request should be filed using the “Request for Administrative Fee Refund” form (Annex 4).

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

2 Reimbursements of costs of expert activities and annual maintenance fees

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

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

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

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

	Czech Republic
Account number	35-623101
Bank code	0710
IBAN	CZ94 0710 0000 3500 0062 3101
BIC (originally SWIFT)	CNBACZPP
Constant symbol	0308
Variable symbol	Generated by the below specified procedure in a manner preventing any duplicities in variable symbols.

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

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

Attachments to the application for an expert activity:

- **"Proof of Payment of Administrative Fee"** form in two copies* (as per part 1 of the Guideline), if an administrative fee is associated with the procedure.

- **"Proof of Payment of Costs for Expert Activities Conducted upon Request"** form in two copies* (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.

2.1.1 Procedure to be applied in the payment of fees for variation to marketing authorisation within mutual recognition procedure:

  - IN case of application concerning grouping of variations type IA (IA_{IN}) for one product the amount is multiplied by the number of variations applied for.
  - In case of application concerning the identical variations type IA (IA_{IN}) for more products the amount is multiplied by the number of variations applied for and by the number of products.
  - In case of annual report (grouping variations type IA) for one product the amount is multiplied by the number of IA variations.
  - In case of annual reporting (grouping of identical IA variations) for more products the amount is multiplied by the number of variations applied for and by the number of products.
  - In case of application concerning group of different types of variations for one product the „highest" amount is paid.
- In case of application concerning grouping of different types of variations to more products the amount for the „highest" type of variations multiplied by number of products is paid.
- In case of „worksharing", when the agency is a reference state, the amount corresponds to the amount paid for type of variation within mutual recognition procedure where CR is the reference member state (RMS), in case it is not a reference member state but concerned member state (CMS) it corresponds to the amount for type of variation valid for CMS variations. to marketing authorisation within mutual recognition issued for a medicinal product by relevant autority of other member state.

Ad IA_{IN}: variation type that requires to be notified immediately (immediate notification – see application for variation to a marketing authorization)

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 and by Section 4 of the Act on Libraries, SÚKL collects reimbursement of costs of activities associated with the provision of information.
The amounts of reimbursements of costs associated with the retrieval of information are provided in the Pricelist (Annex 1, part D). These activities are conducted 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 activity associated with the provision of information. SÚKL shall inform the applicant in writing about the calculation of the activity specifying the amount to be reimbursed prior to the provision of the information. This notice will clearly show the underlying facts for the calculation and the method how the amount has been calculated. Once the applicant confirms in writing the proposed calculation of the activity, incl. the amount of reimbursement, SÚKL shall issue an invoice with details necessary for the bank transfer (variable symbol, bank details for SÚKL). Costs may also be reimbursed by a cash payment made at the SÚKL cash desk.

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

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

4. Reimbursement of other activities

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

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

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

Pricelist of cost reimbursements

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

- Act on Pharmaceuticals – parts A, B, C
- Act on Free Access to Information – part D
- Act on Budgetary Rules – 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..

In case of micro, small or medium enterprise the discount for parts A, B and C can be applied.
Pursuant to Decree No 427/2008 Section 3 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 under letters a)-g).

The applicant shall reimburse the costs in compliance with the applicable legislation of the European Community amounting up to 50% of the amount stipulated in the pricelist for the required expert activity according to part A, B and C; to settle the actual amount within this scope the calculation formula stated in part C should be used. The State Institute for Drug Control (hereinafter referred to as “SUKL”) within the revision of UST-29 has amended the possibility for micro, small and medium enterprise to apply for discount on expert activities pursuant to Decree No 427/2008 Coll., on stipulating the amounts of reimbursement of costs of expert activities conducted within the scope of powers of the State Institute for Drug Control and the Institute for the State Control of Veterinary Biologicals and Medicaments and the process when the duty of annual maintenance fee payment pursuant to Act No. 112 Decree No 378/2007 Coll., on Pharmaceuticals, is not fulfilled.

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

To evaluate the claim for part of the costs to be waived, the applicant shall submit the documentation stipulated in parts a)-g) related to the last accounting period pursuant to Decree No 427/2008 Coll. together with the application to carry out expert activity.
The Documents in points a) b) and c) are not required, when those have been already submitted by the applicant in the same year as part of a different application for expert activity.

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

GENERAL			
Code	**Category**	**Subcategory or specification**	**Amount of costs reimbursement**
U-001	Annual maintenance fee	Conduct of expert activities in respect of the duration of marketing authorisation of a medicinal product with the exception of cases specified under codes U-002, U-003, U-004 and U-005	19 500.00 CZK
U-002	Annual maintenance fee	Conduct of expert activities in respect of the duration of marketing authorisation of a medicinal product where the Czech Republic is the Reference State	39 100.00 CZK
U-003	Annual maintenance fee	Conduct of expert activities in respect of the duration of marketing authorisation of a homeopathic product	6 000.00 CZK
U-004	Annual maintenance fee	Conduct of expert activities in respect of the duration of marketing authorisation of a medicinal product where the marketing authorisation holder is a micro-company	5 000.00 CZK
U-005	Annual maintenance fee	Conduct of expert activities in respect of the duration of marketing authorisation of a medicinal product where the marketing authorisation holder is a small company and homeopathic products are not involved	9 500.00 CZK
O-001	Provision of an hourly oral consultation or issue of a written position in the sphere of regulatory affairs upon request within a scope adequate to an hourly oral consultation (unrelated to a previously submitted application)	Discussion to agree on the details regarding a consultation 0.5 hr, - Preparation of the consultation 3 hrs, - Consultation proper 1 hr, - Activities conducted on the basis of the conducted consultation 1 hr, - Total sum of man-hours 5.50 hrs, - Total costs to be reimbursed 3,100 CZK	3 100.00 CZK
O-002	Provision of an hourly oral consultation or issue of a written expert position upon request within a scope adequate to an hourly oral consultation regarding an issue associated with the operation of the Institute in the sphere of pharmaceuticals.	E.g. a distinction to determine whether a clinical trial is concerned, a position on the use of pure alcohol (per one product), a summary overview of adverse effects of a specific product upon request of the marketing authorisation holder or selected data on authorised products as specified, opinion on possible confusion of the name of a medicinal product requested outside the scope of a marketing authorisation	3 600.00 CZK

		procedure (max. 3 various names for a single product at one time), opinion on proposed advertising of a human medicinal product disseminated by channels other than radio and television broadcasting – preliminary assessment of the advertising materials. - Administrative activities associated with the takeover of the request 0.5 hr, - Preparation for the drafting of the expert opinion proper 5.50 hr, - Administrative activities associated with the sending of the drafted expert opinion 0.50 hr, - Total sum of man-hours 6.50 hr, - Total costs to be reimbursed 3,600 CZK.	
O-003	Provision of an hourly oral scientific consultation or issue of a written expert position upon request within a scope adequate to an hourly oral consultation (unrelated to a previously submitted application)	E.g. an assessment of the design of the proposed clinical study, preclinical testing, analytical method, statistical analysis, expert assessment of proposed texts (SPC, PIL). - Discussion on the details regarding the consultation 0.5 hr, - Preparation for the consultation 20 hrs, - Consultation proper 1 hr, - Activities carried out on the basis of the conducted consultation 1 hr, - Total sum of man-hours 22.5 hrs, - Total costs to be reimbursed 12,500 CZK.	12 500.00 CZK
O-004	Provision of an hourly expert lecture upon request associated with the content of SÚKL's operation (for the sphere of pharmaceuticals).	Dissemination of education (in the sphere of pharmaceuticals) at professional workshops and lectures	12 000.00 CZK

MARKETING AUTHORISATION

Code	Category	Subcategory or specification	Amount of costs reimbursement
R-001	Application for marketing authorisation of a medicinal product	□ separate marketing authorisation based upon complete experimental or literature data (except for separate marketing authorisation specified under R-002), fixed combination	250 000.00 CZK
R-002		□ generic marketing authorisation and marketing authorisation with the approval of another marketing authorisation holder and separate literature marketing authorisation of electrolyte solutions listed under the B05BB01 ATC code, where uncomplicated cases are concerned	200 000.00 CZK
		□ hybrid marketing authorisation, i.e. generic marketing authorisation with data beyond the scope of essential similarity	

		□ simplified registration of a homeopathic product	
		□ registration of a traditional herbal product	
R-003		• marketing authorisation of a completely identical product under another name (duplicate)	70 000.00 CZK
R-004		□ another strength or pharmaceutical form	100 000.00 CZK
R-007	Application for Type II variation to marketing authorisation		70 000.00 CZK
R-008	Application for Type IA variation to marketing authorisation and application for variation of a parallely imported medicinal product		4 700.00 CZK
R-040	Application for Type I B variation to marketing authorisation or change to product labelling or package leaflet unrelated to the summary of the product characteristics		6 700.00 CZK
R-009	Application for renewal of marketing authorisation of a medicinal product.	□ all medicinal products except for homeopathic products	150 000.00 CZK
R-010		□ homeopathic products	75 000.00 CZK
R-011	Application for transfer of marketing authorisation of a medicinal product.		20 000.00 CZK
R-012	Application for authorisation to place a batch of a medicinal product with foreign-language labelling on the market		3 900.00 CZK
R-013	Application of a notified body for the issue of a position on a pharmaceutical forming an integral part of a medical device		33 900.00 CZK
R-014	Application for revocation of marketing authorisation	□ without further requirements	None
R-015		□ with the requirement for phase-out sale	6 100.00 CZK
R-016	Multiple application for marketing authorisation of a medicinal product	□ for the submission of a 2nd or other application for marketing authorisation of a completely identical medicinal product under another name (a replacement for the 1st application shall be paid as per the type of application proper)	23 900.00 CZK
R-017	**MRP - RMS** Application for commencement of mutual recognition procedure for marketing authorisation (where the Czech Republic is the reference Member State) – This application shall be submitted only after the completion of the national marketing authorisation procedure for the relevant medicinal product (R-001 to R-004).	□ separate marketing authorisation based upon complete experimental or literature data (except for separate marketing authorisation specified under R-018), fixed combination	250 000.00 CZK 350 000.00 CZK*
R-018	R-017 – R-018: * If the application for marketing authorisation of a medicinal product, for which the commencement of the mutual recognition procedure for marketing authorisation has been	□ generic marketing authorisation and marketing authorisation with the approval of another marketing authorisation holder and separate literature marketing authorisation of electrolyte solutions listed under the B05BB01 ATC code, where uncomplicated cases are concerned	200 000.00 CZK 300 000.00 CZK*

		applied for (with the Czech Republic being the reference Member State), has been submitted to SÚKL prior to June 5 2003 (as of when the amended Act No 79/1997 Coll., on Pharmaceuticals stipulates the obligation to comply with the guidance issued by the European Commission and by the European Agency for the Evaluation of Medicinal Products), the amount shall be increased by approx. 50% due to the necessary verifications of compliance with all relevant guidelines in the submitted dossier.	 □ hybrid marketing authorisation, i.e. generic marketing authorisation with data beyond the scope of essential similarity □ registration of a traditional herbal product □ registration of a homeopathic product	
R-020			□ another strength or pharmaceutical form	100 000.00 CZK
R-021			□ marketing authorisation of a completely identical product under another name (duplicate)	80 000.00 CZK
R-022		Application for commencement of a repeated mutual recognition procedure for marketing authorisation (where the Czech Republic is the reference Member State).	The processing of this type of application includes both the decision on the relevant variation to or renewal of marketing authorisation and the completion of the mutual recognition procedure for the application in question.	100 000.00 CZK
R-023		Application for Type II variation to marketing authorisation (where the Czech Republic is the reference Member State).	The processing of this type of application includes both the decision on the relevant variation to or renewal of marketing authorisation and the completion of the mutual recognition procedure for the application in question.	100 000.00 CZK
R-024		Application for Type I B variation to marketing authorisation or change to product labelling or package leaflet unrelated to the summary of the product characteristics within the framework of mutual recognition (where the Czech Republic is the reference Member State).	The processing of this type of application includes both the decision on the relevant variation to or renewal of marketing authorisation and the completion of the mutual recognition procedure for the application in question.	13 900.00 CZK
R-025		Application for Type I A variation to marketing authorisation within the framework of mutual recognition (where the Czech Republic is the reference Member State).	The processing of this type of application includes both the decision on the relevant variation to or renewal of marketing authorisation and the completion of the mutual recognition procedure for the application in question.	12 800.00 CZK
R-026		Application for marketing authorisation renewal within the framework of mutual recognition (where the Czech Republic is the reference Member State).	The processing of this type of application includes both the decision on the relevant variation to or renewal of marketing authorisation and the completion of the mutual recognition procedure for the application in question.	200 000.00 CZK

R-027	DECENTRALISED PROCEDURE / MRP - CMS	Application for recognition of marketing authorisation granted for a medicinal product by the concerned authority of another Member State or for recognition of marketing authorisation granted by means of a decentralised procedure.	□ separate marketing authorisation based upon complete experimental or literature data (except for separate marketing authorisation specified under R-028), fixed combination	110 000.00 CZK
R-028			□ generic marketing authorisation and marketing authorisation with the approval of another marketing authorisation holder and separate literature marketing authorisation of electrolyte solutions listed under the B05BB01 ATC code, where uncomplicated cases are concerned	90 000.00 CZK
			□ hybrid marketing authorisation, i.e. generic marketing authorisation with data beyond the scope of essential similarity	
			□ registration of a traditional herbal product	
			□ registration of a homeopathic product	
R-030			□ another strength or pharmaceutical form	40 000.00 CZK
R-031			□ marketing authorisation of a completely identical product under another name (duplicate)	30 000.00 CZK
R-032		Application for Type II variation to marketing authorisation within the framework of mutual recognition of marketing authorisation granted for a medicinal product by the concerned authority of another Member State.		50 000.00 CZK
R-033		Application for Type I B variation to marketing authorisation or change to product labelling or package leaflet unrelated to the summary of the product characteristics within the framework of mutual recognition of marketing authorisation granted for a medicinal product by the concerned authority of another Member State.		4 700.00 CZK
R-034		Application for Type I A variation to marketing authorisation within the framework of mutual recognition of marketing authorisation granted for a medicinal product by the concerned authority of another Member State.		4 700.00 CZK
R-035		Application for marketing authorisation renewal within the framework of mutual recognition of marketing authorisation granted for a medicinal product by the concerned authority of another Member State.		80 000.00 CZK
R-036	Application for parallel import of a medicinal product		□ authorisation for a single country from which the concerned medicinal product is	40 000.00 CZK

			to be imported	
R-037			□ authorisation for any other strength of the same product from the same import country	15 000.00 CZK
R-038			□ authorisation for a single country from which the concerned medicinal product is to be imported, with a more complex assessment of data on therapeutic adequacy (e.g. bioequivalence studies or separate stability studies)	60 000.00 CZK
R-039	Application for renewal of authorisation of parallel import of a medicinal product			30 000.00 CZK
R-041	**DECENTRALISED PROCEDURE - RMS**	Application for commencement of a decentralised marketing authorisation procedure (where the Czech Republic is the reference Member State)	□ separate marketing authorisation based upon complete experimental or literature data (except for separate marketing authorisation specified under R-018), fixed combination	390 000.00 CZK
R-042			□ generic marketing authorisation and marketing authorisation with the approval of another marketing authorisation holder and separate literature marketing authorisation of electrolyte solutions listed under the B05BB01 ATC code, where uncomplicated cases are concerned or hybrid marketing authorisation, i.e. generic marketing authorisation with data beyond the scope of essential similarity • hybrid authorisation, i.e. generic authorisation with data beyond the scope of essential similarity • authorisation of a traditional herbal remedy • registration of a homeopathic product	310 000.00 CZK
R-044			□ another strength or pharmaceutical form (extension of marketing authorisation)	170 000.00 CZK
R-045			□ marketing authorisation of a completely identical product under another name (duplicate)	120 000.00 CZK
R-046	Application for adoption of marketing authorisation from another Member State			None
R-047	Application for renewal of authorisation adopted from another Member State			None
R-048	Application for RMS (change from CMS to RMS)			100 000.00 CZK

INSPECTIONS

Code	Category	Subcategory or specification	Amount of costs reimbursement
I-001	Application for manufacturing authorisation for medicinal products or variations to manufacturing	□ import from third countries	31 700.00 CZK

	authorisation with an inspection A variation to manufacturing authorisation consists of a change to the required type and scope of manufacture, incl. quality control tests which are to be performed or addresses of all manufacturing and quality control sites; where a reduction of the type and scope of manufacture or cancellation of a manufacturing site is concerned, the reimbursement shall be made as for a variation without inspection.		
I-002		□ non-sterile medicinal products – one pharmaceutical form and/or one manufacturing unit/line different in terms of manufacture at a single manufacturing site	48 900.00 CZK
I-003		□ non-sterile medicinal products – any other pharmaceutical form and/or manufacturing unit/line different in terms of manufacture	13 300.00 CZK
I-004		□ sterile medicinal products – one pharmaceutical form and/or one manufacturing unit/line different in terms of manufacture at a single manufacturing site	64 500.00 CZK
I-005		□ sterile medicinal products - any other pharmaceutical form and/or manufacturing unit/line different in terms of manufacture	17 900.00 CZK
I-006		□ an increase of the basic fee for the above-mentioned cases where biotechnological or technologically complex manufacture of biological preparations is concerned	38 600.00 CZK
I-007		□ a separately conducted primary packaging of non-sterile products - one pharmaceutical form and/or one manufacturing unit/line different in terms of manufacture at a single manufacturing site	33 100.00 CZK
I-008		□ a separately conducted primary packaging of non-sterile products - any other pharmaceutical form and/or manufacturing unit/line different in terms of manufacture	13 900.00 CZK
I-009		□ separately conducted secondary packaging at a single manufacturing site	30 600.00 CZK
I-010	Application for variation to manufacturing authorisation for medicinal products without inspection Variations to manufacturing authorisation concern changes to the following details: □ Name(s), surname, place of operation and identification number, if assigned, of the natural person who is applying for this authorisation; where this authorisation is applied for by a legal person, its company/business name, registered office, mailing		9 000.00 CZK

	address, and identification number, if assigned, □ name(s), surname, qualifications and expertise of qualified persons, □ name(s), surname, place of operation and identification number, if assigned, of the natural person who is contracted out to undertake parts of the manufacture or quality control, its company/business name, registered office, mailing address, and identification number, if assigned; In the case of a change to the company registration number (IČ) it is usually necessary to apply for a new authorisation; in the case of a contracted-out manufacture and quality control of medicinal products in third countries where the results of inspection by another authority cannot be recognised, the reimbursement shall be made as for an application for certification of GMP compliance with inspection at a foreign manufacturer's.		
I-011	Application for distribution authorisation for medicinal products or variation to the distribution authorisation with inspection Variations to distribution authorisation concern a change to the requested type and scope of distribution or address of all sites where distribution is conducted. In the event of reduction of the type and scope of distribution or winding-up of a certain site from where distribution is conducted, or in the event of distribution premises reduction without any impact upon their layout, the compensation shall be made as for a variation without inspection.	□ with the inspection of a single warehouse • change to the required type and scope of distribution or addresses of all sites from which distribution is conducted	25 300.00 CZK
I-012		□ for any other warehouse within the scope of a single authorisation	13 300.00 CZK
I-013	Application for extension of distribution authorisation for the distribution of active substances and excipients or for the distribution of blood, its components and intermediate products.	□ with the inspection of a single warehouse	25 300.00 CZK
I-014		□ for any other warehouse within the scope of a single authorisation	13 300.00 CZK
I-015	Application for variation to the distribution authorisation for medicinal products without inspection Extensions of distribution authorisation concern, in particular, the following data changes: □ Change of name, surname or place of operation and identification number, if assigned, of the natural person who is applying for this authorisation, where this authorisation is applied for by a legal person, its company/business name, registered office, mailing address and identification number, if	• restricting the type and scope of distribution or cancellation of a site from which distribution is conducted • reduction of distribution premises without any modification of their layout • change to the name, surname or place of business of a natural person who is the holder of the authorisation • change to the business company, or name, number or mailing address of a legal person • change to the name(s) and surname(s) of the qualified person	7 400.00 CZK

	assigned □ Change of name(s) a surname, qualifications and expertise of the qualified person. Where the identification number is changed, it is usually necessary to apply for a new authorisation.		
I-016	Application for authorisation to engage in an activity as a control laboratory or variation to an authorisation to engage in an activity as a control laboratory with inspection Variations to an authorisation to engage in an activity as a control laboratory concern changes to quality control tests, which are to be conducted, or address of all quality control sites; in the event of abandoning certain authorised quality control tests or winding-up of a quality control site, compensation shall be made analogously to the variation without inspection.	□ partial testing	31 400.00 CZK
I-017		□ full-scope testing (physical, physico-chemical, and chemical testing of pharmaceuticals, or microbiological testing, where applicable)	40 000.00 CZK
I-018	Application for variation to an authorisation to engage in an activity as a control laboratory without inspection Variations to an authorisation to engage in an activity as a control laboratory concern changes to the following details: name(s), surname, place of operation and identification number, if assigned, of the natural person who is applying for this authorisation; where this authorisation is applied for by a legal person, its company/business name, registered office, mailing address, and identification number, if assigned; Where the identification number is changed, it is usually necessary to apply for a new authorisation; in the event of contracted-out controls of pharmaceuticals in third countries where the results of the inspection of another authority may not be recognised, compensation shall be made analogously to that for the application for Certificate of Compliance with GMP Requirements, with the conduct of an inspection at a foreign manufacturer's premises.		9 000.00 CZK
I-019	Application for the authorisation to manufacture transfusion products and starting materials for further production in blood centres or variation to the authorisation to manufacture transfusion products and starting materials for further production in blood centres with inspection	□ manufacture of transfusion products and starting materials for further production	40 000.00 CZK

	A variation to an authorisation of the manufacture of transfusion products and raw materials for further production consists of a change to the required type and scope of manufacture, incl. quality control tests which are to be conducted, or addresses of all manufacturing and quality control sites; where a reduction of the type and scope of manufacture or cancellation of a manufacturing site is concerned, reimbursement shall be made as for a variation without inspection.		
I-020		□ blood or blood component collection only without further processing and/or whole blood production for autotransfusions	27 000.00 CZK
I-021		□ for any other manufacturing site within the scope of a single authorisation	7 400.00 CZK
I-022	Application for variation to the authorisation to manufacture transfusion products and starting materials for further production in blood centres without inspection A variation to an authorisation of the manufacture of transfusion products and raw materials for further production consists of a change to the following data:		9 000.00 CZK
	• name(s), surname(s), place of business and company registration number (IČ), if allocated, of a natural person applying for this authorisation; if this authorisation is applied for by a legal person, the commercial company, or, if applicable, the name, registered office, mailing address and company registration number, if allocated, □ the name(s), surname(s), qualification and practical experience of qualified persons, • the name(s), surname(s), place of business and company registration number (if allocated) of a natural person undertaking part of the manufacture or quality control on the basis of a contract; for a legal person the commercial company, or if applicable the name, registered office, mailing address and company registration number, if allocated;		

	• in the case of a change to the company registration number it is usually necessary to apply for a new authorisation; in the case of a contracted-out manufacture and quality control of pharmaceuticals in third countries where the results of inspection by another authority cannot be recognised, the reimbursement shall be made as for an application for certification of GMP compliance with inspection at a foreign manufacturer's.		
I-023	Application for Certificate of Compliance with the Conditions of Good Manufacturing Practice in the manufacture of medicinal products, import from third countries, operation of control laboratory, and good distribution practice for the holders of relevant authorisations		1 700.00 CZK
I-024	Application for Certificate of Compliance with the Conditions of Good Manufacturing Practice for a specific medicinal product	Certificate for a Pharmaceutical Product in the WHO scheme.	2 200.00 CZK
I-025	Application for Certificate of Compliance with the Conditions of Good Manufacturing Practice in the manufacture of active substances	□ with the inspection of a single manufacturing unit/line	38 900.00 CZK
I-026		□ for any other manufacturing unit/line	13 300.00 CZK
I-027	Application for Certificate of Compliance with the conditions of Good Laboratory Practice or Good Clinical Practice	□ partial testing, studies using physical, chemical and biological testing systems with the exception of laboratory animals • survey of the clinical site, sponsor, and laboratories in order to assess compliance with the conditions of good clinical practice	31 400.00 CZK
I-028		□ studies using laboratory animals	38 900.00 CZK
I-029	Application for revocation of authorisation to engage in an activity		None

I-030	Application for Certificate of Compliance with GMP Requirements, with the conduct of an inspection at a foreign manufacturer's ("Certificate") If the applications for GMP certificates requiring an inspection at a foreign manufacturer's premises are submitted as part of the marketing authorisation procedure for a medicinal product of the concerned manufacturer, they shall be handled regardless of the pending marketing authorisation procedure. Applications for marketing authorisation without adequate evidence of compliance with GMP requirements may not be successfully completed, and it is therefore pointless to submit at the same time or subsequently Type I-030 application to complete verification of the GMP compliance in parallel with the pending marketing authorisation.	Where it is possible to conduct several inspections within the scope of a single journey, several applicants may share the reimbursement of travel expenses and costs of stay.	Reimbursement as per the requested type of inspection incremented by 20% + reimbursement of travel expenses and costs of stay.
I-031	Application for the issue of certificate of compliance with the conditions of: □ good manufacturing practice in the manufacture of active substances □ good laboratory practice without on-site inspection		1 700.00 CZK

PHARMACIES, VENDORS, LABORATORY ANALYSES, BATCH RELEASE

Code	Category	Subcategory or specification	Amount of costs reimbursement
L-001	Application for Certificate of Compliance with the conditions of Good Practice of Vendors of Selected Pharmaceuticals		7 400.00 CZK
L-002	Application for the issue of certificate of adequate material and technical facilities of a pharmacy	□ for pharmacies starting in new premises	22 100.00 CZK
L-003		□ for pharmacies starting in premises of a formerly authorised pharmacy or starting a satellite dispensing unit for pharmaceuticals and medical devices	7 400.00 CZK
L-004	Application for variation in the scope of operation of a pharmacy in the certificate or for withdrawal of the certificate of adequate material and technical facilities of a pharmacy or an application for a formal change to details in the certificate		1 500.00 CZK
L-005	Laboratory analysis upon request		compensation as per the applied methods (part B of this Annex)
L-006	Application for Certificate of Compliance with the Conditions of Good Laboratory Practice		22 100.00 CZK
L-007	Retesting a batch of a medicinal product prior to its release onto the market	□ with the submission of a certificate issued by an EU Member State	800.00 CZK

L-008		□ without the submission of a certificate issued by an EU Member State	800.00 CZK + compensation as per the applied methods (part B of this Annex)
L-009	Issue of a pharmacopoeia reference substance with a certificate upon request	□ per one bottle	800.00 CZK

CLINICAL TRIALS, THERAPEUTIC PROGRAMMES, DISTINCTIONS BETWEEN PHARMACEUTICALS AND OTHER PRODUCTS

Code	Category	Subcategory or specification	Amount of costs reimbursement
K-001	Authorisation of a clinical trial on a medicinal product	□ Application for authorisation of a clinical trial on a medicinal product The reimbursement of costs in this amount shall be payable also if the formerly authorised/notified study is not commenced within 12 months and major changes to the originally submitted documentation occur.	67 300.00 CZK
K-002		□ Notification of a clinical trial on an authorised medicinal product (30 days) The reimbursement of costs in this amount shall be payable also if the formerly authorised/notified study is not commenced within 12 months and major changes to the originally submitted documentation occur.	15 800.00 CZK
K-003		□ Other notifications of a clinical trial on a medicinal product (60 days) The reimbursement of costs in this amount shall be payable also if the formerly authorised/notified study is not commenced within 12 months and major changes to the originally submitted documentation occur.	33 900.00 CZK
K-004	Sponsor's notification of an amendment to Protocol. Amendment to the Protocol requiring assessment due to a major change to the Protocol, which is likely to affect the safety of trial subjects or to alter the scientific hypothesis of the concerned clinical trial or if the change is significant for another reason. The costs shall be reimbursed in this amount even if the previously authorised/notified study has not commenced within 12 months and minor changes to the originally submitted documentation are made		15 800.00 CZK

K-005	Application for the issue of a position on the conditions of use of a medicinal product, method of its distribution, dispensing, and monitoring and the evaluation of its quality, safety, and efficacy within the scope of a specific therapeutic programme.		15 800.00 CZK For urgent opinions advance payment shall not be required.
K-006	Application for the issue of a decision whether the product is a pharmaceutical, incl. a distinction between a medicinal product and an active substance, a medicinal product subject to marketing authorisation or another product, or, if applicable, a homeopathic product.		6 900.00 CZK

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

Item	Test	Service reimbursement
1	Clarity and degree of opalescence of liquids – for each examined unit	40.00 CZK
2	Degree of coloration of liquids – for each examined unit	40.00 CZK
3	Potentiometric determination of pH	810.00 CZK
4	Relative density	1 010.00 CZK
5	Refractive index	810.00 CZK
6	Optical rotation	1 010.00 CZK
7	Viscosity – using a capillary viscosimeter	1 620.00 CZK
8	Viscosity - using a rotation viscosimeter	1 620.00 CZK
9	Viscosity – using a falling-ball viscosimeter	1 210.00 CZK
10	Distillation range	610.00 CZK
11	Boiling point	610.00 CZK
12	Determination of water by distillation	610.00 CZK
13	Melting point – capillary method	
13a	*For a labelled substance*	610.00 CZK
13b	*For an unlabelled substance*	1 210.00 CZK
14	Drop point	610.00 CZK
15	Freezing point	610.00 CZK
16	Potentiometric titrations	1 620.00 CZK
17	Fluorimetry	2 020.00 CZK
18	Absorption spectrophotometry infrared	2 830.00 CZK
19	Absorption spectrophotometry ultraviolet and visible	2 020.00 CZK
20	Thin-layer chromatography	
20a	*Qualitative determination – for each system*	1 130.00 CZK
20b	*Semi-quantitative determination – for each system*	1 740.00 CZK
21	Gas chromatography	
21a	*Simple determination*	5 660.00 CZK
21b	*Complex determination*	6 460.00 CZK
22	Liquid chromatography	
22a	*Simple determination*	5 040.00 CZK
22b	*Complex determination*	7 460.00 CZK
23	Exclusion chromatography	
23a	*Exclusion chromatography of albumin*	10 040.00 CZK
23b	*Exclusion chromatography of immunoglobulins*	12 740.00 CZK
24	Electrophoresis	4 040.00 CZK
25	Loss on drying	1 620.00 CZK
26	Osmolality	1 010.00 CZK
27	Potentiometric determination of fluoride concentration using ion-selective electrodes	1 620.00 CZK
28	Conductivity	810.00 CZK
29	Ion and group identity testing	480.00 CZK
30	Smell	200.00 CZK
31	Ammonium	480.00 CZK
32	Arsenic	2 020.00 CZK
33	Calcium	480.00 CZK
34	Chlorides	480.00 CZK
35	Fluorides	480.00 CZK
36	Magnesium	480.00 CZK
37	Magnesium and alkaline-earth metals	480.00 CZK
38	Heavy metals	480.00 CZK

39	Iron	480.00 CZK
40	Phosphates	480.00 CZK
41	Potassium	480.00 CZK
42	Sulphates	480.00 CZK
43	Sulphated ash	2 420.00 CZK
44	Total ash	2 420.00 CZK
45	Free formaldehyde	
45a	*method A*	480.00 CZK
45b	*method B*	1 620.00 CZK
46	Identification and control of residua solvents	6 460.00 CZK
47	Residual ethylene oxide and dioxan	6 460.00 CZK
48	Acid value	1 210.00 CZK
49	Ester value	1 210.00 CZK
50	Hydroxyl value	1 210.00 CZK
51	Iodine value	1 210.00 CZK
52	Peroxide value	1 210.00 CZK
53	Saponification value	1 210.00 CZK
54	Determination of nitrogen by sulphuric acid digestion	4 040.00 CZK
55	Complexometric titrations	1 010.00 CZK
56	Water semi-microdetermination	2 020.00 CZK
57	Phenol in immunosera and vaccines	1 620.00 CZK
58	Oxidising substances	1 010.00 CZK
59	Total protein	1 620.00 CZK
60	Disintegration of tablets and capsules (without determination)	
60a	*Disintegration in water*	400.00 CZK
60b	*Disintegration is gastric juice*	1 010.00 CZK
60c	*Disintegration in duodenal juice*	1 820.00 CZK
61	Disintegration of suppositories and pessaries (without determination)	400.00 CZK
62	Dissolution test for solid pharmaceutical forms (without determination)	
62a	*Short-term dissolution*	1 010.00 CZK
62b	*Long-term dissolution*	4 850.00 CZK
63	Dissolution test for transdermal patches (without determination)	4 850.00 CZK
64	Uniformity of mass of single dose preparations – for each weighted amount	100.00 CZK
65	Friability of uncoated tablets	400.00 CZK
66	Resistance to crushing of tablets	200.00 CZK
67	Ethanol content	6 460.00 CZK
68	Test for methanol and 2-propanol	6 460.00 CZK
69	Test for extractable volume of parenteral preparations	200.00 CZK
70	Uniformity of mass of individual doses in multiple-dose packaging	100.00 CZK
71	Uniformity of dose units	100.00 CZK
72	Volumetric determination of substances	
72a	*Titration*	1 010.00 CZK
72b	*Retitration*	1 210.00 CZK
72c	*Titration in heterogeneous environment*	1 210.00 CZK
72d	*Titration in anhydrous environment (without isolation)*	1 210.00 CZK
73	Weighing of individual doses of medicines – for each weighted amount	100.00 CZK
74	Macroscopic description, appearance	200.00 CZK
	CONTROL OF RADIOPHARMACEUTICALS	
75	Determination of RA substance identity by half-life	3 230.00 CZK
76	Gamma-ray spectrum	2 830.00 CZK
77	Radioactivity	1 210.00 CZK
78	Radionuclidic purity by gamma-ray spectrum	2 830.00 CZK
79	Radiochemical purity by paper chromatography	3 230.00 CZK

80	Radiochemical purity by thin layer chromatography	3 230.00 CZK
81	Radiochemical purity by liquid chromatography	7 460.00 CZK
82	Radiochemical purity by extraction to organic phase	1 620.00 CZK
83	Radiochemical purity by filtration	3 230.00 CZK
84	Radiochemical purity by gel column chromatography	3 230.00 CZK
85	Radiochemical purity by half-life	3 230.00 CZK
86	Specific radioactivity	1 610.00 CZK
87	Clarity and degree of opalescence of liquids – radioactive substances (for each examined unit)	200.00 CZK
88	Macroscopic description and appearance of RA substances	400.00 CZK
89	Weighing of individual doses of RA substances – for each weighted amount	810.00 CZK
	PREPARATORY AND AUXILIARY ACTIVITIES	
90	Preparation for analysis	1 010.00 CZK
91	Preparation of comparative or tested solution	610.00 CZK
92	Preparation of radioactive sample for analysis	1 210.00 CZK
93	Radionuclide-labelling of non-radioactive substances	2 020.00 CZK
94	Disposal of radioactive waste (for each 40 MBq)	1 010.00 CZK
	MICROBIOLOGICAL AND BIOLOGICAL TESTS	
95	Sterility	
95a	*Sterility – direct inoculation to substrates (products without antimicrobial effects)*	1 210.00 CZK
95b	*Sterility – direct inoculation to substrates (products with antimicrobial effects)*	1 410.00 CZK
95c	*Sterility – membrane filtration method*	2 210.00 CZK
95d	*Sterility of antibiotics - membrane filtration method*	2 210.00 CZK
96	Microbiological testing of non-sterile products (total count of live aerobes)	
96a	*Microbiological testing of non-sterile products – Category 2*	2 020.00 CZK
96b	*Microbiological testing of non-sterile products – Category 3B*	2 020.00 CZK
96c	*Microbiological testing of non-sterile products – Category 4A*	1 620.00 CZK
96d	*Microbiological testing of non-sterile products – Category 4B*	2 020.00 CZK
96e	*Aqua purificata microbiological quality test*	810.00 CZK
96f	*Biochemical strain typization*	610.00 CZK
97	Bacterial endotoxins	1 620.00 CZK
98	anti-A a anti-B hemagglutinins – indirect method – (indirect Coombs test)	2 830.00 CZK
99	Immunochemical methods	
99a	*Methods in which a labelled antigen or a labelled antibody is used (ELISA)*	4 040.00 CZK
99b	*Immunoprecipitation methods – Ouchterlony*	4 040.00 CZK
99c	*Immunoprecipitation methods – Mancini*	2 420.00 CZK
100	Abnormal toxicity	
100a	*Basic*	2 020.00 CZK
100b	*Of immunosera and vaccines*	3 020.00 CZK
100c	*Specific*	2 830.00 CZK
101	Assay of tetanus vaccine adsorbed	70 000.00 CZK
102	Identity tests, tests of thermal stability and assay on tissue cultures	
102a	*Monovaccine*	5 460.00 CZK
102b	*Divaccine*	7 850.00 CZK
102c	*Trivaccine*	13 090.00 CZK
103	Cytotoxicity on tissue cultures	11 850.00 CZK
104	Skin-irritability test of substances (pursuant to ISO)	22 040.00 CZK
105	Sensitisation test with a closed patch	22 040.00 CZK
106	Efficacy test of lyophilised complement	2 830.00 CZK
107	Efficacy test of haemolytic amboceptor	2 830.00 CZK

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

C. Calculation formula

Costs in CZK = x . b

where:

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

b = costs of 1 hour of work incl. payroll, costs of materials, services, and domestic travel costs, which are **556 CZK** for the costs of the Institute.

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

Item	Service description	Service reimbursement	Unit
1	**Copy services**		
1a	*A4 copy – one side*	2.00 CZK	piece
1b	*A4 copy – both sides*	4.00 CZK	piece
1c	*A3 copy – one side*	4.00 CZK	piece
1d	*A3 copy – both sides*	8.00 CZK	piece
1e	*Scanning - A4 format*	2.00 CZK	piece
2	**Mailing services**		
2a	*Sending a letter by regular post (up to 20g)*	20.00 CZK	piece
2b	*Sending a letter by registered mail (up to 20g)*	39.00 CZK	piece
2c	*Other deliveries*	20.00 CZK	piece + postal charges
3	**Inter-library loan service (MVS)**		
3a	*Book unit loan from the library*	Free of charge	
3b	*Copies from books*	20.00 CZK	Price for each set (even if incomplete) of 10 pages of the original
3c	*Copies from the database*	20.00 CZK	Price for each set (even if incomplete) of 10 pages of the original
4	**Literature search**		
4a	*Print output*	Item 1 refers	
4b	*CD output*	10.00 CZK	piece
5	**Information**		
5a	*From paid databases*	As per the current pricelist of Dialog, Thomson business, see http://support.dialog.com/pricing/	

6	**Reimbursement of costs for data searches and processing**		
6a	*Literature search*	556.00 CZK	For each hour, even if incomplete
6b	*Information*	278.00 CZK	For 0.5 hr.
6c	*Information*	556.00 CZK	From 0.5 to 1.0 hr.
6d	*Information*	556.00 CZK	For any following hour, even if incomplete
7	**SÚKL Annual Report**		
	Printed Annual Report	70.00 CZK	piece

E. Reimbursement for other services

Item	Item name	Reimbursement of the service in CZK	
		per 1 hr. (even if incomplete)	**Per 1 day (8 hr. max.)**
1	**Assembly hall rental**	500.00 CZK	3500.00 CZK
2	**Equipment hire**		
2a	*Screen*	100.00 CZK	500.00 CZK
2b	*Overhead projector*	50.00 CZK	200.00 CZK
2c	*Laser pointer*	10.00 CZK	50.00 CZK
2d	*Flipchart (incl. paper)*	50.00 CZK	150.00 CZK
2e	*Writing aids for Flipchart*	20.00 CZK	60.00 CZK
2f	*PC use*	150.00 CZK	600.00 CZK
2g	*Audio technology use*	150.00 CZK	600.00 CZK
2h	*Data projector*	500.00 CZK	2 000.00 CZK
2f	*Technical background*	556.00 CZK	4 448.00 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 IČO, applicants with registered office abroad fill in the registration number under which the company has been incorporated in the country of its domicile, or the VAT number (DIČ).
Items marked with * are mandatory.

Applicant:

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

Payer's bank account number *:

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

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

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

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

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

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

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

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

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

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

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

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

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

Applicant:

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

Payer's bank account number *:

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

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

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

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

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

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

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

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

Code of type of application – Pricelist of cost reimbursements

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).*

Application for administrative fee refund

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

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

**) Please complete only if known

Date _____ Applicant's name and signature _____

2.3 Do not complete – for SÚKL's internal use

I agree/disagree with the refund of the amount of: CZK

Rationale – see the Decision on the refund of an administrative fee ref. no. .....dated.....

Date _____ Name and signature of SÚKL section manager _____

Accountancy records: