UST-24 version 10 Reimbursement of costs of expert activities conducted upon request – waivers and refunds; provision of expert information to competent authorities

This guideline supersedes Guideline UST-24 version 9 with the effect from 12 January 2023.

The Guideline is published with regard to and in compliance with the provisions of Section 112 of 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 Pharmaceuticals"); Section 27 of Act No 296/2008 Coll., on Safeguarding the Quality and Safety of Human Tissues and Cells Intended for Use in Man and on Amendments to Related Acts (Act on Human Tissues and Cells), as amended (hereinafter referred to as the "Act on Human Tissues and Cells"); Act No 375/2022 Coll., on Medical Devices and In Vitro Diagnostic Devices, as amended (hereinafter referred to as the "Act on Devices"); Section 39f, paragraph 16 of Act No 48/1997 Coll., on Public Health Insurance, as amended (hereinafter referred to as the "Act on Public Health Insurance"); and Section 24g, paragraph 2 of Act No 167/1998 Coll., on Dependency-Producing Substances and on Amendments to some Acts, as amended.
The guideline is of the nature of a recommendation.

1. Waiving the reimbursement of costs upon request

The State Institute for Drug Control (hereinafter referred to as the "Institute") **shall**, for no other reasons than those referred to under Section 112, paragraph 3, letter (b) of Act on Pharmaceuticals and under Section 27, paragraph 3, letter b) of Act on Human Tissues and Cells, **fully or partly waive** the reimbursement of costs if associated with activities:

- performed in relation to adoption of marketing authorisation or
- whose conduct is in the public interest or
- which may have particularly significant implications for a broad range of persons.

The Institute shall waive the reimbursement of costs **only on the basis** of a fully completed application form signed by the authorised person and sent to the Institute´s Accounting Department (UCT). This application form for waiver of reimbursement of costs is provided under Annex 1 hereto.
If any of the lawful reasons applies to the case in question, the applicant shall submit, together with the application for the expert activity, an application for waiving of the reimbursement of costs in the form of a cover letter, giving reasons in compliance with Section 112 of the Act on Pharmaceuticals and Section 27 of the Act on Human Tissues and Cells. The applicant shall always provide a proof of specific facts which support his/her claim and shall provide a reference to information sources where his/her claim may be verified. In all cases, the Institute shall check whether the lawful reasons for waiving the reimbursement have been fulfilled. Where the Institute rejects to waive the reimbursement, it shall invite the applicant to reimburse the costs pursuant to Guideline UST-29, UST-36.

Examples of situations when the reimbursement of costs may be waived are provided below:

a) Applications for authorisation/notification of clinical trials on pharmaceuticals, where the submitter is a doctor working in a state healthcare facility, a state healthcare facility, a university, the state via its organisational unit, a professional medical society, the Czech Medical Chamber, the Czech Dental Chamber, or the Czech Pharmaceutical Chamber;
b) Consultations and opinions in respect of the cases referred to under section a);
c) Applications pertaining to orphan medicinal products;
d) Consultations and opinions in respect of applications pertaining to orphan medicinal products and medicinal products intended for use solely in persons under the age of 18 years;
e) Acts carried out upon request of entities which are subject to support pursuant to directly applicable Community regulations (e.g. Regulation of the European Parliament and of the Council (EC) No 726/2004).

2. Refunds of reimbursed costs based on a request

2.1. Upon request

2.1.1. Pursuant to the Act on Pharmaceuticals and pursuant to the Act on Human Tissues and Cells, the Institute refunds reimbursements of costs on the basis of a fully completed application form signed by the authorised person and sent to the Institute´s Accounting Department (UCT). This application form is provided under Annex 1 hereto.
In compliance with Section 66 paragraph 2 of the Act on Devices, the Institute shall refund reimbursement of costs to the applicant on the basis of a fully completed application signed by the authorised person and sent to the Institute's Accounting Department (UCT). This application form is provided under Annex 2 hereto.

The Institute shall fully or partially refund the reimbursed costs to the applicant in any of the following cases:

a) If the applicant has reimbursed the costs without being obliged to do so, the Institute shall refund the full amount;
b) If the procedure or the requested expert activity have not commenced at all, the Institute shall refund the full amount;
c) If the applicant has paid a higher amount than the one established in the Pricelist of reimbursements of costs (guideline UST–29, UST-36), the Institute shall refund the difference between the two amounts;
d) If the applicant had paid and thereafter, upon his/her consequent request, the Institute waived the reimbursement of costs, the Institute shall refund the difference between the requested and waived amount of reimbursement;
e) If an administrative procedure is suspended upon the applicant's request or on the Institute's initiative, or if an expert activity carried out outside the scope of an administrative procedure is terminated upon the applicant's request or on the Institute's initiative, the Institute shall refund an amount of the reimbursed costs which is proportionate to the expert activities which have not yet been conducted at the time of termination of the processing of the request; if an assessment report has already been drafted or comments from all assessors involved have been prepared, all expert activities shall be rendered completed.

2.1.2. In compliance with the requirements set fort by Section 24g of the Act on Dependency-Producing Substances, upon the applicant´s request, the Institute shall refund the full amount of cost reimbursement, if the applicant paid the cost reimbursement without being obliged to or if the required activity was not commenced, or in the amount corresponding to the proportionate part of the paid cost reimbursement for those expert activities that were not performed. Cost reimbursement may be refunded only on the basis of a fully completed application signed by the authorised person and sent to the Institute´s Accounting Unit (UCT). The application form is provided in Annex 3 hereto.

2.2. Automatically

Pursuant to the provisions of Section 39f, paragraph 16 of the Act on Public Health Insurance, the Institute shall refund the cost reimbursement:

a) In full amount, if the applicant has paid cost reimbursement without being obliged to do so;
b) In full amount, if the requested expert activity has not commenced or the expert consultation was not given; or
c) In an amount proportionate to the cost reimbursement amount paid for expert activities that were not performed.

The Pricing and Reimbursement Regulation Section (CAU) shall monitor cost reimbursements on an ongoing basis and should the authorised CAU staff find out that a cost reimbursement is to be refunded partially or in full, they shall instruct the Accounting Unit (UCT) to refund the fee, giving the reason therefor.

3. Refunds of reimbursed costs as an overpayment based on incorrect payments without request

The Institute shall refund incorrectly sent payments, due to an aggregated payment received with several variable symbols and in the case of duplicate and unrequested payments. The appropriate amount shall be matched with the respective variable symbol and the difference shall be refunded.
Should the amount to be refunded amount to less than 500 CZK, the Institute shall not refund the reimbursement, fully or partially.

4. Provision of expert information to competent authorities

The Institute shall provide expert information to competent authorities **without the obligation to reimburse the costs**, specifically to:

- Law enforcement authorities in the conduct of their tasks, without unnecessary delay and unless a special regulation stipulates otherwise, incl. **without consideration** (Section 8, paragraph 1 of Act No 141/1961 Coll., on Criminal Judicial Procedure (the Code of Criminal Procedure);
- Czech Police who is authorised to request, within the scope necessary for the fulfilment of a specific task, material and personal assistance from **public administration authorities**, particularly the necessary source materials and information, including personal data; these authorities are obliged to provide the requested assistance (Section 18 of Act No 273/2008 Coll., on the Czech Police);
- Czech customs administration authorities who may request, within the scope necessary for the fulfilment of a specific task within the execution of their powers, the necessary source materials and information, including personal data from other **public administration authorities**; these authorities are obliged to provide the requested assistance (Section 58, paragraph 6 of Act No 17/2012 Coll., on the Czech Customs Administration).

If any of the lawful reasons applies to a particular case, together with the application for expert activity, the applicant shall submit an application for waiver of the reimbursement of costs in the form of a cover letter, justified in compliance with Section 8, paragraph 1 of Act No 141/1961 Coll., on Criminal Judicial Procedure (the Code of Criminal Procedure)or Section 18 of Act No 273/2008 Coll., on the Czech Police or Section 58, paragraph 6 of Act No 17/2012 Coll., on the Czech Customs Administration. The applicant shall always evidence specific facts supporting the claim. In any and all cases, the Institute shall check whether the lawful reasons for waiving the reimbursement of costs have been met. Where the Institute does not waive the reimbursement, it shall invite the applicant to pay the reimbursement of costs in compliance with Guideline UST-29.

Annexes

Annex 1: Application for waiver/refund of reimbursement of costs pursuant to the Act on Pharmaceuticals and the Act on Human Tissues and Cells

Annex 2: Application for refund of reimbursement of costs pursuant to the Act on Medical Devices an Act on In Vitro Diagnostic Medical Devices

Annex 3: Application for refund of cost reimbursement pursuant to the Act on Dependency-Producing Substances

Application for waiver/refund of reimbursement of costs pursuant to the Act on Pharmaceuticals and the Act on Human Tissues and Cells

For clear identification of your request, please complete all the fields!

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

**) Please state the marketing authorisation number in case of requests for the refund of the annual maintenance fee, or for the refund of reimbursements of costs of any procedure relating to a previously authorised medicinal product*

**) *Procedure number in case of mutual recognition procedures*

****) Variable symbol specified in the "Proof of Payment of Cost Reimbursement" document*

_____ _____

Date Applicant's name and signature

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

Position of the unit carrying out the expert activity on the rationale stated in the application: ……

With a view to the aforementioned, I consent/do not consent to the refund of: CZK ……

_____ _____

Date Name and signature of the operation' mandator

Application for refund of reimbursement of costs pursuant to the Act on Medical Devices an Act on In Vitro Diagnostic Medical Devices

For clear identification of your request, please complete all the fields!

Application file no.		
Expert activity (for categories, see UST-29):		
Code (see UST-29):		
Name of the assessed product:		
Content of the application		
Applicant's name:		
Applicant's address:	Street, PO Box:	Town, Postcode, State:
Contact person:		
Contact person's address:		Phone, email:
Amount to be refunded (in CZK):		Date of payment:
Variable symbol of the application *)		Requested currency of refund:
Name of Applicant's bank:		Address:
Account no/bank code:		IBAN:
SWIFT:		National clearing code**:
Rationale:		

**) Variable symbol specified in the "Proof of Payment of Cost Reimbursement" document*
***) If known*

Date

Applicant's name and signature

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

Position of the unit carrying out the expert activity on the rationale stated in the application: …….

With a view to the aforementioned, I consent/do not consent to the refund of: CZK ……

Date

Name and signature of the operation mandator

Application for refund of cost reimbursement pursuant to the Act on Dependency-Producing Substances

For clear identification of your request, please complete all the fields!

Application file no.		
Expert activity (for categories, see UST-29):		
Code (see UST-29):		
Specification of the content of the application:		
Applicant's name:		
Applicant's address:	Street, PO Box:	Applicant's address:
Contact person:		
Contact person's address:		Phone, email:
Amount to be refunded (in CZK):		Date of payment:
Variable symbol of the application *)		
Name of Applicant's bank:		Address:
Account no./bank code:		IBAN:
SWIFT:		National clearing code – if known:
Rationale:		
Reference to sources where the statement may be verified		

**) Variable symbol specified in the "Proof of Payment of Cost Reimbursement" document*

_____ _____

Date Applicant´s name and signature

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

Position of the unit carrying out the expert activity on the rationale stated in the application: …….

With a view to the aforementioned, I consent/do not consent to the refund of: CZK ……

_____ _____

Date Name and signature of the operation mandator