

UST-24 version 6 Reimbursement of costs of expert activities conducted upon request – waivers and refunds

This guideline replaces UST-24 version 5 with effect from 1 January 2017.

Waiving the reimbursement of costs

The State Institute for Drug Control (hereinafter referred to as the “Institute”) shall, pursuant to no other reasons than stated in Section 112, paragraph 3, letter (b) of Act No 378/2007 Coll., on Pharmaceuticals, as last amended (hereinafter referred to as the “Act on Pharmaceuticals”) and pursuant to Section 27, paragraph 3, letter b) 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), 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 wide scope of persons.

The Institute shall consider waiving of the reimbursement of costs **only if requested to do so**. Where the applicant considers himself/herself to be entitled to the waiving of the reimbursement of costs, he/she shall submit, together with the application for the expert activity an application for waiving of the reimbursement of costs in the form of an attached letter giving reasons in compliance with the provisions of Section 112 of the Act on Pharmaceuticals and Section 27 of Human Tissues and Cells. The applicant shall always provide a proof of specific facts which support his/her claim, or shall provide a reference to information sources where his/her claim may be verified. In all cases the Institute shall assess whether mandatory 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 clinical trial authorisation/notification, 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 case 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 of support pursuant to directly applicable Community regulations (e.g. Regulation of the European Parliament and of the Council (EC) No 726/2004)

Refunds of reimbursed costs based on a request

The Institute refunds cost based on a signed request sent to the Accounting department (UCT) of the Institute. The Request Form is attached as Annex No 1 to this guidance.

The Institute shall fully or partially refund the reimbursed costs to the applicant in 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 activity have not commenced at all, the Institute shall refund the full amount;
- c) If the applicant has paid a higher amount than established in SUKL Pricelist (guideline UST–29, UST-36), the Institute shall refund the difference between the two amounts;

- d) If the applicant has paid and consequently upon his request the Institute has waived the reimbursement of costs, the Institute shall refund the full amount,
- e) If an administrative procedure is suspended upon the applicant's or the Institute's request or if an expert activity carried out outside the scope of an administrative procedure is terminated upon the applicant's or the Institute's request, 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 the processing of the application; if an assessment report has been prepared, all expert activities shall be rendered completed;

Refunds of reimbursed costs based on wrong payment.

The Institute will refund wrongly sent payments without prior request and in the case of aggregated payment using more variable symbols. The appropriate amount shall be attributed to the given variable symbol and the difference shall be refunded.

Should the amount to be refunded be less than 500 CZK, the Institute shall not refund it.

Application for Refund of Reimbursement of Costs

Please fill in all the fields to clearly identify your application!

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

*) Please state the registration number in application for the refund of the annual maintenance payment, or for the refund of reimbursements of costs of any proceedings relating to medicinal product already registered

**) Number of procedure for mutual recognition procedures

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

Date

Applicant's name and signature

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

Position of the division carrying out the expert activity on the reasoning of the application:

Therefore I consent/do not consent to the refund of: CZK

Date

Name and signature of the operation' mandator

Records of the economic department