UST- 20 version 1
Application for an Opinion on a Specific Therapeutic Programme

This guideline is replacing UST-20 version 0, effective date from 1. 11. 2020.

The guideline has been issued based on Section 49, Paragraph 2 of Act No. 378/2007 Coll., On Pharmaceuticals and on Amendments to Some Related Acts (hereinafter "the Act on Pharmaceuticals") and Section 2, Paragraph 1 of Decree 228/2008 Coll., On Registration of Medicinal Products. The guideline specifies the procedures for submitting a correct and complete application for an Opinion on a Specific Therapeutic Programme (hereinafter "STP").

The instruction has a **recommendatory character**.

Where in the cases specified in a directly applicable EU regulation or in other emergencies a human medicinal product authorised pursuant to this Act or pursuant to a directly applicable EU regulation is not available for the effective treatment of patients, prophylaxis and prevention of infectious diseases or for diagnostic purposes, the use, distribution, and dispensing of human medicinal products not authorised pursuant to this Act or pursuant to a directly applicable EU regulation may be permissible for the treatment, prevention or diagnosing of rare diseases or in other emergencies within the scope of STP. STP may be proposed, if:

a) the subject of the STP is the treatment, prophylaxis and prevention or diagnosing of conditions which present a serious threat to human health;
b) the use of the non-authorised medicinal product is in compliance with STP designed in advance, which defines, in particular:
    1. the medicinal product to be used,
    2. the manufacturer of the medicinal product, or, where applicable, the distributor or the person importing the medicinal product from third countries,
    3. the group of patients for whom the medicinal product is intended and method of use of the medicinal product,
    4. the method of quality, safety, and efficacy monitoring and evaluations of the medicinal product and of the therapeutic benefit of its use,
    5. the sites where the therapeutic programme is conducted,
    6. the rationale of STP.

Technical and organization information

1. Link to the website

- Electronical form:
  Application for an Opinion on Specific Therapeutic Programme | Státní ústav pro kontrolu léčiv (sukl.cz)

- General information related to STP:
  Specific Therapeutic Programmes, State Institute for Drug Control (sukl.eu)

- Installation package eSigner for the application signature and instructions for use (available in Czech language only):
  Rozšířená verze instalačního balíčku komponenty eRecept Signer | Elektronické preskripce (epreskripce.cz)

2. Instructions for completing, signing, and submitting the form

Fill out the individual fields of the form, you can find help for some fields under the question mark, mandatory fields are marked with *.

Recommendation:
Before submitting the form save the completed form on your computer (using the *Save the form* button). In case of any problem with submission, it will no longer be necessary to fill out the form again. The saved file can also be used to refill the form easier.
The form has been saved in JSON format. Do not make any changes in the saved files, otherwise the form does not load. A form is loaded from the file saved from your computer by clicking the *Load the form* button.
Note: you have uploaded attachments to the form, the attachments have not been saved and you will need to reattach attachments after loading form from the saved file.

Please upload the submitted documentation/attachments to the appropriate fields by *Choose files* button or by dragging the file. In the field can be uploaded up to 20 files.

In case of technical problems with the form signature, it is possible to download the unsigned form in PDF format (after filling all mandatory fields) and it can be sent by the electronic mail room to the Institute, for more detail please see Electronic mail room, State Institute for Drug Control (sukl.eu), or the form can be printing and signing, delivered to the Institute´s filling office.

You can sign the form with an electronic signature. Firstly, please verify if you have a valid and properly installed qualified certificate or save the certificate in a P12 or PFX file. The signature should be done by using the eSignature application. The installation package, installation information and other information you find under the link (available in Czech language only): Rozšířená verze instalačního balíčku komponenty eRecept Signer | Elektronické preskripce (epreskripce.cz)

Use the *Submit the electronically signed form* button to submit the electronical signed form. You will receive information about the electronic submission to the e-mail address mentioned in the application. Information contains PDF file confirming the electronic submission and PDF file of the submitted application for an opinion on Specific therapeutic program proposal.

3. Support

Below you can find the support contacts related to STP submitting application.

- Please send the specific questions related to the content of the application to the e-mail: marketreport@sukl.cz
- Please send the issues with the signature done by application eSigner and general technical questions to the e-mail: podporaformularu@sukl.cz