Guideline
for electronic submission
of Applications
(eVariation)

Version: 4.3
Contact: evar@sukl.sk

Technical requirements:
Internet browser   Microsoft IE 6.0 and higher, Mozilla Firefox 3.0 and higher
Internet Access   minimal connection speed 100 KB/s
Screen resolution   1024x768 and higher
E-mail account   for receiving of notifications from eApplication Portal

Introduction

The application Electronic Submission of Applications (eApplication) has three main aims:
 1) provision of a variable symbol that client and SIDC use as an identifier of payment
 2) electronic tracking of transfers of fees
 3) provision of basic specific standard data from applications in electronic form

Version 4.3

The new version 4.3 applies the new way of fee determination. There is a further sign of the determination of the pharmaceutical form or strength, the importance of which depends on the type of application:
 - change of the pharmaceutical form and strength for application for Marketing Authorisation
 - another strength for the variation application.
 In the new version the position of Slovak authority as RMS or CMS is specified.

Appearance of the screen

1.   Left menu – crossing to the home page of e Application, creation of new Application, entering an existing Application, information on Application submission.
2.   Basic steps of Application submission.
3.   Operation the Application – contents of single steps.
4.   Status of the Application – information on the Application status.

Electronic Application submission procedure

Phase I   Filling-in the Application Form and assignment of the Variable Symbol
          Step 1. Type of Application choice
          Step 2. Filling-in the Application Form
          Step 3. Completion of data in the Application
Phase II   Fee payment
          Step 4. Print out confirmation of the Variable Symbol assignment
Phase III   Delivery of the documentation to the SIDC
Detailed description of particular Steps is presented below.

Step I. Filling-in the Application Form and assignment of the Variable Symbol

For filling-in the Application Form and assignment of the Variable Symbol is intended the portal **eApplication** at the address:
https://portal.sukl.sk/evarsym/index.php. When submitting new Application, choose in the Main Menu the item **"NEW APPLICATION"**. For the entry to an existing Application choose **"ENTER APPLICATION"**. When entering into an existing Application you will be asked for entering the Variable Symbol and the Control Code assigned.

Step 1. Application type

- Choose the requested type of Application.
  If you want to submit a grouped variation Application, enter this as the variation of the highest type (i.e. if the group of variations consists of types IA + IB + II, choose type II variation). With all types of Applications except of new Marketing Authorisation Application it is necessary to fill-in the Marketing Authorisation Number of the medicinal product.

Step 2. Application

- With some types of Application you will be asked to fill-in the Marketing Authorisation Number of the medicinal product.

- Fill-in the Form with data. The basic parts of the Form are: Applicant, Contact person, Drug eventually other blocks concerning the particular type of Application. The data you fill-in the Form must be the same as in the Application, and some of them is not possible to change any more. If the Application is filled-in incorrectly, establish new Application do not use the button "Back" in the browser.

  The box e-mail in the part **"Contact person"** fill-in with valid e-mail address where all messages from *evar@sukl.sk* will be sent (receipt of the Application, receipt of the fee, information on overcharge, information on undercharge, recording of the Application -

State Institute for Drug Control,
                                      Kvetná 11, 825 08 Bratislava 26

Evidence Number assignment). If you fill-in an incorrect e-mail address you will not be able to proceed submitting of the electronic Application.

In the part Type of change (by variation Applications) you may enter the variation typed two ways:
- fill-in the codes of variations directly to the text field. Confirm by clicking *"Enter"* or
- choose the individual types of variations from the choice list by clicking *"Choose"*.

With several types of Applications complete characteristic of the medicinal product (name of medicinal product, form, strength, type of medicinal product, legal basis) is entered in the **part "Drug"**. With Application types "variation" you must enter the Marketing Authorisation Number of the medicinal product concerned and click "Verify".
You may add-on more medicinal products by clicking the text *"Add"*.

In the part Fee the calculation of price is stated. The fee depends on different indicators like type of process, number of medicinal products, legal basis, specification of the position of Slovak authority as RMS or CMS, information regarding to another strength and pharmaceutical form, etc., therefore it is necessary to fill-in these data before the calculation of the fee itself. For the fee update click *"Fee recalculate"*. Adequacy of sign of another strength or pharmaceutical form will be evaluated after saving of the application (see Step 3 Data completion, The Medicinal product/s status).

In the part **"Data confirmation"** reply the coloured letters to the appropriate field. If you are not able to read them, click *"If you cannot read these characters, click here"*. You have 10 attempts to enter the control symbol then you must close the browser window.

- After filling-in the Application continue with clicking *"Save"*. The Application may not be save until the data is filled-in correctly. The incorrectly filled-in data is announced with an error message.

- Subsequently the system will assign you the **Control code**. Via the dialogue window you will be asked to print out the Control code. Print the Control code out immediately or save it in your PC as this **will not be sent** to your e-mail.

- You will get an e-mail to the address of Contact person with your **Variable symbol**, which you will use by payment. The printed out e-mail with the assigned Variable symbol **does not serve** as an annex to the Application!

Carefully store the Control code and the Variable symbol. You will need them by your further work with the Application.

NOTE: Even after obtaining the Variable symbol you may come back to your Application and change the data within. When you change the data having impact on the fee calculation, the information on new fee will be sent to the e-mail of Contact person.

Step 3. Data completion

In the upper part of the screen is a recapitulation of Application data. These data you may change by clicking the "*Step 2. Application*" in the left menu. Under the recapitulation individual documents that need to be annexed are stated with red letters:

- Annex the document "Application" by clicking the text "Add application" (see the picture below).

- Annex the other documents relating the medicinal product by clicking the text with the name of the document (see the picture below).
  Mandatory documents are highlighted with red bold letters. Add them by clicking the highlighted text. Non-mandatory documents are highlighted with bold letters. You may add them by clicking the highlighted text. If you wish to re-write the original document, load it by clicking the text with the name of the document. Previous document will be replaced by the new one.
  If you wish to delete particular document, expand the list of documents by the arrow: ⏬ and delete the selected line.

- Open the Card of basic data by clicking the text "Sentence" (see the picture below). You may load the data from the SIDC database to the Card of basic data with the help of the button "*Data initialization*", or you may load the data you saved in your PC with "*Load from my computer*". Fill-in all items to the Card. If you wish to save the filled-in data choose *"Save to my computer"*. Send the filled-in Card of basic data by clicking *"Send"*.
  In the part **Contact person responsible for communication during the registration** - fill-in the e-mail correctly, because after the receipt of the Application the announcements will be sent to this e-mail address exclusively. When filling-in **the data on the manufacturer** fill-in the name of the manufacturer first (the first 3 letters of the name may be sufficient), and the system will automatically offer you the list of manufacturers.
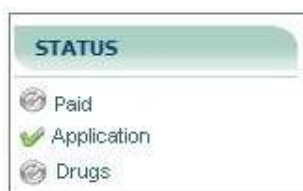
Picture: Annexing of documents to the Application
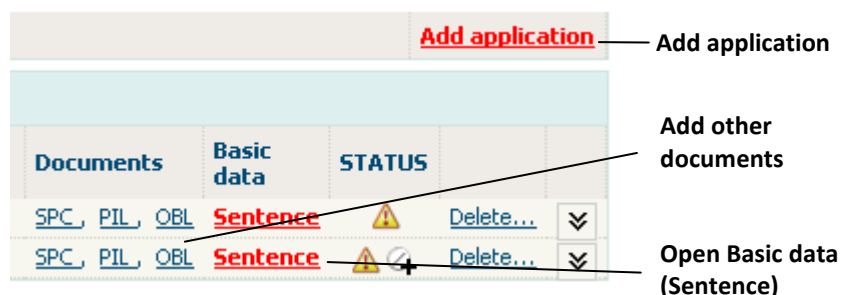
Status

There are two types of status in the application eApplication:
The Application status – information on the status of the Application which is localised in the upper right part of the screen:

The Medicinal product/s status – shows the information on the annexed documents status and on the basic data (Sentence Card) status. Meaning of icons in the status:

⚠ mandatory document is not annexed and/or the basic data card (Sentence Card) is filled-in incorrectly.

✔ mandatory document is annexed and the basic data card (Sentence Card) is filled-in correctly.

⊘ non-mandatory document is not annexed

- information regarding adequacy of sign of another pharmaceutical form and strength:

⊘➕ another pharmaceutical form and strength

⊘➕❓ incorrectly filled out another pharmaceutical form and strength

Phase II. The fee payment

The value of the fee and the Variable symbol needed for the payment are stated in the message **Confirmation on Variable symbol assignment** that was sent to the e-mail address of the Contact person.

During several days after the fee payment from the evarsymbol@sukl.sk a message will be sent to the e-mail address of the Contact person, confirming the payment eventually the difference accrued.

Step 4. Application confirmation print

Print out the **Confirmation on the Variable symbol assignment**. This Confirmation is needed to be submitted to the SIDC together with all the documentation.

The Confirmation is printable only if the Application is filled-in completely (Step 2. Application) and all data is filled-in the Application simultaneously (Step 3. Data completion).

Phase III. Submission of the documentation to the SIDC

Documentation requested:
Application and annexes to the Application (SPC, PIL...),
Confirmation of the Application.

Subsequently a message confirming the receipt of the Application and Evidence Number assignment will be sent to the e-mail address of the Contact person.