

Vigilance Form User Manual

General comments and warnings

It is advisable to use the latest browser versions. The operation of the application is guaranteed for the following browsers: Internet Explorer 8 and higher, Firefox 23 and higher, Chrome 29 and higher. The use of other browsers may cause problems.

For navigation in the application use **only buttons and links within the scope of the application. Never use the Back button in the browser frame** - in case of using, you will be advised to this effect and brought back to the start of completion. Furthermore, you will lose any unsaved data.

The screenshot shows the SÚKL Vigilance Form application interface. At the top left is the SÚKL logo. Below it is a navigation bar with several buttons: 'Download data' (callout 2), 'Upload test data' (callout 3), 'Clear all form data' (callout 4), and 'Upload XML file' (callout 1). The 'Upload XML file' button is highlighted in blue and has a red circle with the number 1 next to it. Below the navigation bar is a section titled '1. Administrative information'. It contains a text input field for 'Name of National Competent Authority (NCA)' with the value 'Státní ústav pro kontrolu léčiv (SÚKL)'. The input field is highlighted in yellow and has a red circle with the number 5 next to it. There is also a question mark icon (callout 6) next to the 'Date of this report' label.

Report completion

The vigilance form application is intended exclusively for online report completion.

Forms may be completed in several ways:

- By completing the items.
- By filling sample data in the form using the *Upload test data* button [3]. Data filled in this manner serve only as an example of individual item completion for better understanding of their meaning. Please note that once you press the *Upload test data* button [3], any previously completed data will be deleted and replaced with the sample data!
- To upload the XML of an existing data file use the *Upload XML file* button [1], the application will complete the items from the XML file. Please note that once you press the *Upload XML file* button [1], any previously completed data will be deleted and replaced with data from the XML file! More information on saving XML data files is provided below.

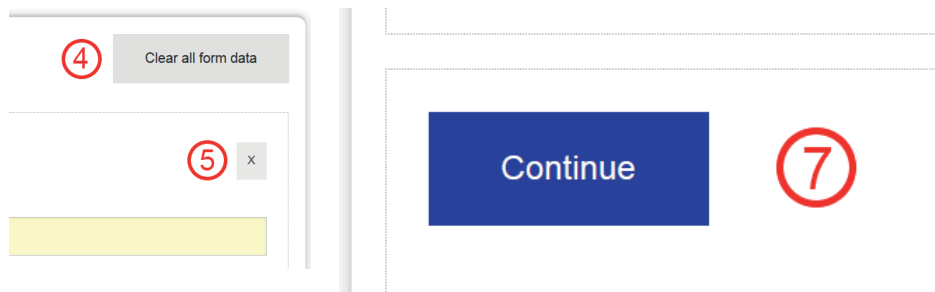
Fields highlighted in yellow are mandatory and the application will require their completion.

Some fields require information in a certain format (e.g. date). A help is displayed by placing the mouse cursor over the question mark [6] next to the field name.

A close-up of the 'Date of this report' field. The label 'Date of this report' is followed by a question mark icon (callout 6) and a yellow input field.

At any time during completion, you can save the entered data in the XML format for further use if you click on the *Download data* button [2]. This function enables the creation of templates with basic data that subsequently will not have to be entered repetitively. At this moment the application does not validate saved data. These saved data may be uploaded to the form from the XML data file by using the *Upload XML file* button [1].

At any time during the entry it is possible to delete the data from the form (except of default data, e.g. the National competent authority name) using the *Clear all form data* button [4]. It is also possible to delete only one section in the thin grey frame using the cross symbol in the upper right hand side corner of the respective section frame). [5].



After completing the form and final check of the content press the *Continue* button [7] (this action does not submit the form yet).

If any mandatory field is not completed (is empty) or in invalid format, the application will display a list of identified errors in the form with reference to the item. By clicking on the error name in the list of the uncompleted fields the application will move the cursor to the field which requires completion. For example:

*Please complete the field `Reference number assigned by manufacturer`.
Invalid data format in field `Date of this report` (please use
YYYY-MM-DD).*

Working with completed data

Next step options will be displayed after all data have been completed correctly.

Save the completed form in the PDF format for future use by pressing the *Download PDF file* button [9]. Check the contents of filled fields in the PDF form.

Save the XML data file equally by pressing the *Download XML file* button [10]. This file will contain validated XML data.

Use the *Modify filled data* button [8] to go back to the pending form and make any necessary changes. After completing the changes, save the forms again in the PDF and XML formats as above.

The report form was filled in.

If necessary, it is possible to **modify or add information filled in the form**.

Please **download the form in PDF and XML file** for checking the completed data and for the possibility of further processing.



Signing of the form

Download the completed form in the PDF format to your computer using the *Download PDF file* button [9].

Insert a certified electronic signature of the authorised person (reporter's statutory body or the person provided with the power of attorney or authorised by the statutory body for representation in the vigilance system for medical devices) to the PDF form.

To sign the form, you may for example avail of means Adobe Acrobat Reader version 11 and higher, or use any other method you are used to.

Methods of submission of the form to SÚKL

Act No. 62/2015 Coll., implementing some provisions of the Act on Medical Devices allows for the submission of the completed form the following ways:

- a) via web interface;
- b) by means of a data message; or
- c) by electronic mail.

a) Submitting the form via web interface

Attaching the signed form

1. Sign the PDF as instructed above.
2. You can upload the signed PDF form back to the application by selecting the signed file and pressing the *Attach signed PDF* button [11].



Adding attachments

Up to 5 attachments of the maximum total size of 7MB may be attached to application using the web interface. Permitted attachment formats are the following: DOC, DOCX, RTF, ODT, ODS, PDF, XLS, and XLSX.

To add an attachment, select the required file in the attachment section and press the *Attach annexes* button [12].

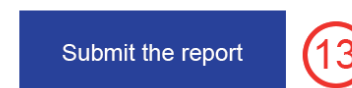
Following successful upload of the file, a link to each of the uploaded attachments will be displayed and you can check whether you have uploaded the correct files.

To submit the form via web interface it is not necessary to attach the file of the completed data in the XML format. The XML data file will be sent automatically upon submission to SÚKL.

Form submission to SÚKL

By pressing the *Submit the report* button [13], the form will be submitted to SÚKL. After the submission the completed form will no longer be available, therefore please check whether you have saved both the PDF and XML formats of the form in your computer prior to the submission.

If the submission has been successful, information announcing that the data have been successfully submitted will be displayed.



b) Submitting the form by means of a data message

If you select this option, send the XML file, signed PDF form and any other attachments, if applicable, to SÚKL via the Data Box. SÚKL Data Box identifier is qwfai2m.

c) Submitting the form by electronic mail

If you select this option, send the XML file, signed PDF form and any other attachments, if applicable, to SÚKL via e-mail to posta@sukl.cz.