

FAQ for DIS-13

1. The link to the new DIS-13 form for manual entry does not want to let me in. The page states that I need a certificate.

The form is a certificate-protected form, you must first generate a security certificate on the pristupy.sukl.cz portal and install it on your computer.

2. What access information should I use to generate a certificate on the portal pristupy.sukl.cz?

Use the access information you received when your request for access as a Distributor was approved. The access information is composed of Request number (Login name) and PIN (Password). You need to enter this access information at the login page to External Identity portal https://pristupy.sukl.cz/ei_forms.html#/login in order to generate a certificate. After successful login, the system prompts you to create a new password.

3. I have no access to the External Identity portal pristupy.sukl.cz.

If you are a new distributor or you have lost your login information, please fill out the request for new access information <https://www.sukl.eu/medicines/zadost-o-zrizeni-uctu> and send it to informatika@sukl.cz.

4. Why should I enter a new password to generate the certificate when I successfully got to the portal for external identities on pristupy.sukl.cz?

Logging into the portal allows you to manage your certificates. It is necessary to create a password for each SSL certificate you generate. You will need to enter this password during installation of the certificate to your computer. Remember the password for later use (e.g., downloading and installing the certificate to another PC). **For practical reasons, do not enter diacritics when creating a password.** If you forget your password, you have to deactivate the certificate (red button "Invalidate" / "Zneplatnit") and generate a new certificate.

5. I enter the External Identity portal and download the certificate, but I do not know the password.

It is possible that someone else in your company has generated the certificate. Therefore, it is necessary to ask the person who generated the certificate for the password to install the certificate. If you do not get this password to install the certificate, you have to deactivate the certificate (log into External Identity portal https://pristupy.sukl.cz/ei_forms.html#/login and press red button "Invalidate" / "Zneplatnit" next to the certificate) and generate a new certificate.

6. I have a certificate, but the DIS13 report form is still unavailable.

If DIS13 is still unavailable, you may have an incorrectly installed certificate. First, install the certificate on your computer. You must double-click on the certificate file. This will launch the installation assistant. There is no need to modify any parameters, it is only necessary to enter the password to install the certificate at the appropriate step. You entered this password on the External Identity portal when generating the certificate. If you have forgotten this password, you have to deactivate the certificate (log into External Identity portal https://pristupy.sukl.cz/ei_forms.html#/login and press red button "Invalidate" / "Zneplatnit" next to the certificate) and generate a new certificate. After installing the certificate, you need to restart your browser. In some cases, you also need to clear the Cache in your browser.

7. I downloaded the certificate and immediately signed in DIS13 but after logging in, it reported an error to me: The workplace does not have DIS13.

If you entered the DIS13 form immediately after generating the certificate, the workplace will not be written in the DIS13 in many cases so quickly. Each certificate must be linked to the

workplace and the synchronization takes up to one day. In this case, please try again to open the DIS13 the next day.

8. I have taken all the necessary steps to get to the form, but DIS13 is not working for me.

Please write a request to email itpodporahlaseni@sukl.cz, indicating your ID, the code of the workplace and a detailed description of your problem.

9. I'm in the form, but I do not know how to enter the report.

The best solution is to watch the video on the SÚKL portal: pristupy.sukl.cz in the video section where you will find instructional videos on how to enter the report.

After opening the form, on the first page you will find information about your subject and individual tiles with your workplaces or workplace. For each workplace, you can immediately see at the bottom of the tile whether you have reported for the given month or not. If you click on a workplace for which you have not reported yet, a window will pop up with the option to enter a report or a non-distribution declaration. After choosing whether to enter a classic report or declaration, the confirmation button directs you to the editing section. If you do not want to enter the report immediately, you can close the window. In that case, you will find the button: "Create report" displayed above the list of reports. Click "Create report" to get to the editing window.

You can start the report for the current month until the 5th of the following month. In the list of reports, the status of the report is displayed as 'Open'. After the 5th day of the month, the status of the report is "Closed" and the report can no longer be edited.

10. How do I make a declaration of non-distribution of medicinal products for my workplace?

You have three options on how to proceed in order to file a declaration of non-distribution for the current month by the 5th of the following month:

- a) You can enter a non-distribution declaration after clicking on your selected workplace. If you have not yet reported for the workplace, clicking on the workplace will open a window with the option of selecting a report or a non-distribution declaration. After selecting the report or declaration button, the declaration for the given month will be automatically created and sent to SÚKL.
- b) A non-distribution declaration can be created in the list of reports by a button located above the list: "Create report". You can access the list of reports by clicking on the tile of the selected workplace on the main page where you will find the List of Workplaces.
- c) A non-distribution declaration may also be generated from the report automatically by removing all items of registered and unregistered medicinal products. In the list of reports, the "Type" column should be changed to "Declaration"

A declaration can be changed to a report by adding new medicinal products.

11. How do I know that the report is really sent to the SÚKL.

All entries in the report form are part of the report. Each item is automatically sent to SÚKL after filling in and confirming by the button: "Save". (The confirmation appears for a few seconds in the form of a green window on the bottom right with the text: "The medicinal product has been saved"). At any time, it is possible to log into the form again and check or correct the data. To check the data, you can use the following:

- a) Preview for older months using the icon: "Preview" or for the current month, the pencil icon: "Edit".
- b) The Excel spreadsheet, which you can download by clicking on the Excel icon, also on the right side of the report.
- c) You can also request an email confirmation of the reported report by using the green envelope icon on the right side of the report: "Send email notification". Once you have

entered your email address, you should receive a confirmation by email about your report or declaration.

12. How do I change the declaration of non-distribution to report?

If you have entered a declaration of non-distribution and need to change it for the current month to report and enter distributed medicinal products, just click on the pencil icon: "Edit" on the right side of the report and start typing the medicinal products. Once you enter at least one medicinal product, the "Type" column in the list of reports changes from "Declaration" to "Report". For the older months, it is no longer possible to change declarations in this way and it is necessary to enter an extraordinary report (see extraordinary reports below).

13. It is after the 5th of the month and I failed to enter the report.

It is necessary to send an official request with the identification of the distribution company, workplace code and reasons for your request to the email oda@sukl.cz. Subsequently, SÚKL employees will enter a non-distribution declaration. If you wish to change the declaration to report, you need to enter an extraordinary report (see extraordinary reports below).

14. It is after the 5th of the month and I have not been able to make the changes that occurred during the review of the report.

The report allows for the creation of so-called extraordinary reports. Extraordinary reports are part of the form and the automated application interface.

15. How do I make an extraordinary report?

You can create an extraordinary report for all older months and for the current month after the reporting period has expired. An extraordinary report can be initiated by clicking on the red wrench icon: "Create extraordinary report for this report" on the right side of the report. When you click on the wrench icon, you enter the explanation, email, phone, and press the button: "Create". Extraordinary reports work by copying the original report you have submitted, and you only edit the original as needed. However, in the case of extraordinary reports, the individual items are not automatically sent to SÚKL, but you need to enter / correct all items first and then send them all to SÚKL by pressing the button: "Send extraordinary report" at the top of the form.

You may also want to delete the entire extraordinary report using the button at the top of the extraordinary report: "Delete extraordinary report".

After sending the extraordinary report to SÚKL, you will be returned to the list of reports. At the bottom of the list of reports, you will find a table called "Extraordinary reports", where you will find all extraordinary reports and you can easily find out whether your report is open for editing, sent to SÚKL or approved / refused by SÚKL.

Once the extraordinary report is approved or refused by SÚKL, it is possible to create another extraordinary report for the month, and the wrench icon on the report for the given month is again red and not inactive gray.

16. Is it possible to print the report?

In the list of reports, for each report you will find the arrow icon: "Download excel file". You can easily check the downloaded file (in XLSX format) and print it if needed.

17. How do I find out what to enter?

For the DIS-13 form, in the footer (bottom of the page), you have a link to the DIS-13 instruction, where you will learn how to proceed with the correct entries.

(Direct link: <https://www.sukl.eu/medicines/dis-13-version-8>).

18. I do not understand the meaning of some items even after I read the instruction.

Please send a request for explanation to email oda@sukl.cz.

19. Can I find some simple instructions on how to proceed with DIS-13 reporting?

On pristupy.sukl.cz, you can find instructional videos on how to proceed with reports or declarations of non-distribution. You can also read instructions at <https://www.sukl.eu/medicines/dis-13-version-8>.

20. I have MS WinXP, I cannot install the certificate / I cannot get to the form.

The security certificate does not work on Windows XP. You must have Windows 7 or higher, or a third-party OS that meets security requirements.

21. In which browsers does the DIS13 form work?

DIS13 works flawlessly on **Chrome**, **Firefox** and **Edge** browsers.

22. Where can I get further support?

Questions about external identity at SÚKL and requests for restoring access – EI@sukl.cz

Technical support for external identity at SÚKL and certificates – pristup@sukl.cz

Technical support for online forms REG13 and DIS13 – itpodporahlaseni@sukl.cz

Administrative questions and questions about content of DIS13 and REG13 forms – oda@sukl.cz

Client-oriented solution development support – <https://kc.sukl.cz> Registration is needed for entering.