FAQ for REG-13

1. The link to the new REG-13 manual entry form 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 "Marketing Authorisation Holder" at https://pristupy.sukl.cz/ei_forms.html#/form_Reg 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.
Please request new access information as a "Marketing Authorisation Holder" on pristupy.sukl.cz and send the completed request to the SÚKL office using one of the following options:

a) print the downloaded PDF request, sign it, scan it and send it by email to posta@sukl.gov.cz,
b) print the downloaded PDF request, sign it, put it in an envelope and send it by post to the State Institute for Drug Control, Šrobárova 49/48, 100 00 Prague 10 or deliver it personally to the filing office,
c) sign the downloaded PDF request electronically with a qualified electronic signature and send it by email to posta@sukl.gov.cz,
d) send the downloaded PDF request to the SÚKL databox: qwfai2m.

(Direct link to the request: https://pristupy.sukl.cz/ei_forms.html#/form_Reg)

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 REG13 report form is still unavailable.
If the REG13 form 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 logged in to the REG13 form, the logon was done smoothly, but unfortunately there is no workplace in REG13, so I cannot report.
In case you entered the REG13 form immediately after generating the certificate, the certificate contents do not go into the REG13 form so quickly. Every certificate must be linked to the holder's address, and the synchronization takes up to one day. In this case, please try again to open the REG13 form the next day.

8. I have taken all the necessary steps to get to the form, but the REG13 form does not work.
Please write your request to email itpodporahlaseni@sukl.gov.cz, indicating your ID, your workplace code and a detailed description of your problem, including a screen shot.

9. I'm in the form, but I do not know how to enter the report.
The best solution is to watch the video for REG 13 on the SÚKL portal: pristupy.sukl.cz in the video section where you will find instructional videos on how to enter the report.
Once you have opened the form, you will find information on your subject. You can immediately see at the tile if you have reported or not for the month. If you click on the tile that has not been reported yet, a window will pop up with the option of selecting a report or a declaration of non-delivering. 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 this case, the window will appear every time you view the list of reports.
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-delivering of medicinal products?
You have two options on how to proceed in order to file a declaration of non-delivering for the current month by the 5th of the following month:

a) You can create a declaration of non-delivering of medicinal products after clicking on the tile of your workplace. If you have not reported yet, clicking on the tile will open a window with the option of selecting a report or a declaration of non-delivering of medicinal products. After selecting the report or declaration button, the declaration for the given month will be automatically created and sent to SÚKL.
b) The declaration of non-delivering can also be created from the report automatically by removing all items of registered medicinal products. In the list of reports, "Report" should be changed to "Declaration " in the TYPE column.

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) You can download a PDF file using the PDF icon, also on the right side of the report.

c) You can also request an email confirmation of the reported report by using the envelope icon on the right side of the report. 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-delivering to report?
If you have entered a declaration of non-delivering and you need to change it for the current month to report and enter delivered medicinal products, simply 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 Holder, workplace code and reasons for your request to the email oda@sukl.gov.cz. Subsequently, SÚKL employees will create a declaration of non-delivering of medicinal products. 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 you to create 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 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 bin icon next to the extraordinary report.
All extraordinary reports can be found on the "Extraordinary reports" tab, where you will find all the 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 active again.

16. Is it possible to print the report?
You can download a PDF confirmation of the report, which gives a summary of the items reported. Due to the large volume of data to be reported, it is no longer possible to download the report in tabular form, which would contain all the details of the items reported.

17. 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://sukl.gov.cz/en/guidelines-general-guidelines-en/ust-46-2/.

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.gov.cz.

19. Can I find some simple instructions on how to proceed with a REG-13 report?
On pristupy.sukl.cz, you can find instructional videos on how to proceed with reports or non-delivery declarations. You can also read instructions at https://sukl.gov.cz/en/guidelines-general-guidelines-en/ust-46-2/.

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 REG-13 form work?
REG-13 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.gov.cz
Technical support for external identity at SÚKL and certificates – pristup@sukl.gov.cz
Technical support for online forms REG13 and DIS13 – itpodporahlaseni@sukl.gov.cz
Administrative questions and questions about content of DIS13 and REG13 forms – oda@sukl.gov.cz
Client-oriented solution development support – https://kc.sukl.cz Registration is needed for entering.