

FAQ version 2 REG-13

1. The reference to the new REG-13 manual entry form does not want to let me in. The page reports 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 should I use the access data to generate a certificate on the portal [www.pristupy.sukl.cz](https://pristupy.sukl.cz)?

Use the "Registration Holder" request type, Received Request Number and PIN. The data can only be used after approval of the access request by a SÚKL employee.

https://pristupy.sukl.cz/cert_request.html#/request

3. I have no access to the External Identity Portal.

Please inquire about the access data on the portal.sukl.cz, the "Marketing Authorization Holder" application.

https://pristupy.sukl.cz/portal/#/form_Reg

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

If you successfully enter a password on the pristupy.sukl.cz website in the External Identity portal, you still need to enter the password for your SSL certificate. Remember this password or save it for later use or download of the SSL certificate (eg re-downloading the certificate to another PC, etc.). Do not enter diacritics for practical reasons when entering a password.

5. I enter the External Identity portal, but I already have the certificate generated, ie in the STAY state, but if I download it, I do not know the password.

In this case, someone else in your company has generated a certificate. If your distributor is your company, someone could generate a certificate within the distribution activity report. Therefore, it is necessary for the person who generated the certificate to ask for the password to install the certificate. If you do not get this password to install the certificate, please contact us at pristup@sukl.cz.

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 downloaded 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 in the appropriate step. You entered this password into the External Identity Portal when generating the certificate. If you have forgotten this password, please contact pristup@sukl.cz. After installing the certificate, you need to restart Google Chrome. In some cases, you also need to clean it in the Cache 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 can not report the REGtribution.

In case you entered the REG13 form immediately after generating the certificate, the certificate contents do not go into the REG13 form so quickly, so every certificate must be linked to the holder's address, and the synchronization takes 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 application to email itpodporahlaseni@sukl.cz, indicating your ID, or 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 SIDC portal:

<https://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 and the individual tiles with your warehouses, only one stock. For each store, you can immediately see the tile at the bottom of the tile if you are reported or not for the month. If you press a warehouse that has not been reported yet, a window with the option of selecting a message or a non-delivery statement is called up. After choosing whether to report a classic report or statement, the confirmation button directs you directly to the edit section. If you select the option to enter the message later, the button: "Create Report" is displayed above the list of messages. Click "Create report" to get to the editing window.

You can start the report by the 10th of the month and you have the status: "Open". Between the 10th and the 20th of the month, you can still correct the report, and in the status of the report you have a status indication: "To edit"

10. How do I make a statement about the non-delivery of medicinal products in my warehouse?

You have three options:

a) You can create a statement about the non-submission of the LP by the 10th day of the month after you have pressed your chosen warehouse. If you have not yet been notified, pressing the selected store will open a window with the option of selecting a report or a statement about not delivering the LP. After selecting the report or statement button, you will automatically be placed in the reporting list for a given month and sent to SUKL.

b) The LP failure statement can be created in the message list by a button located above the message list: "Create Report". You can access the list of messages by pressing the tile of the selected store on the main page where you will find the List of Workplaces.

c) A LP not to report can also be created from the report automatically by removing all items of registered LPs. In the message list, "Report" should be changed to "Statement" in the TYPE column.

The statement can be changed to the report by adding new medicines.

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 automatically after filling in and confirming 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 medicine was saved"). Whenever it is possible to re-enter the form and recheck data, repair. The check is to:

a) Preview in older months using the icon: "Preview" or " for the current month, the pencil icon: "Edit".

b) Download the Excel spreadsheet, which you can download by pressing the Excel icon, also on the right side of the report.

c) You can also request an email confirmation of the reported message by using the green envelope icon on the right side of the message: "Send an email notification". Once you have an email address, you should be sent a confirmation of your message or statement.

12. How do I change the statement about not delivering a LP on a report?

If you have entered a non-LP statement and you need to change it for the current month to report and enter distributed medicines, simply press the pencil icon: "Edit" on the right side of the message and start typing the medication. Once you have entered at least one medicinal product, the "Type" column from "Statement" to "Message" will change in the message list. In the older months, it is no longer possible to change this way and it is necessary to apply for an extraordinary repair of SÚKL (see extraordinary repairs below).

13. It is after the 10th of the month and I failed to enter the report.

It is necessary to send an official application with the identification of the distribution company and the workplace code to the email oda@sukl.cz. Subsequently, SÚKL employees will create a statement about the non-submission of the LP, which you will be able to change to the 20th of the month and edit it.

14. It is after the 20th of the month and I have not been able to make the changes that occurred during the review of the report.

The report allows us to create so-called extraordinary repairs.

Exceptional repairs are part of the form and the automated application interface.

15. How do I make an extraordinary repair?

Exceptional repair is possible for all older months and for the current month after the 20th of the month. An extraordinary repair can be initiated by pressing the red key icon: "Create an extraordinary correction for reporting" on the right side of the report. When you click on the key icon, you enter the justification, mail, phone, and press the button: "Create". Exceptional repairs work by copying the original report you have submitted, and you are only editing the original as needed. However, in the case of extraordinary repairs, the individual items are not automatically sent, but you will either enter or correct all items first and then send them to SÚKL by pressing the button: "Submit correction for approval" at the top of the form.

If you are making an extraordinary repair of an existing report, the original items from the report are copied to you in exceptional repair and you can only repair the items and then send them to SÚKL.

You may also want to delete the extra patch with the button at the top of the extra patch: "Delete extraordinary repair"

After sending the correction 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 repairs", where you will find all the extraordinary repairs and you can easily find out whether your repair is open for your editing, sent to SIDC or Saccu approved or rejected.

Once the correction is approved or rejected by SÚKL, it is possible to create another extra correction for the next month, and the red key on the reporting for the given month is again stained with inactive gray red.

16. Is it possible to print the report?

In the list for each report you will find the arrow icon: "Download Excel File". You can easily print and check the report.

17. How do I find out what to enter?

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

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

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

19. Can I find some simple 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 reporting, non-delivery declaration.

20. I have MS WinXP, I can not install the certificate / I can not 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.

21. In what browsers does the REG-13 form work?

REG-13 works flawlessly on Chrome Firefox and Edge browsers, but unfortunately IE reports in some cases faulty links.