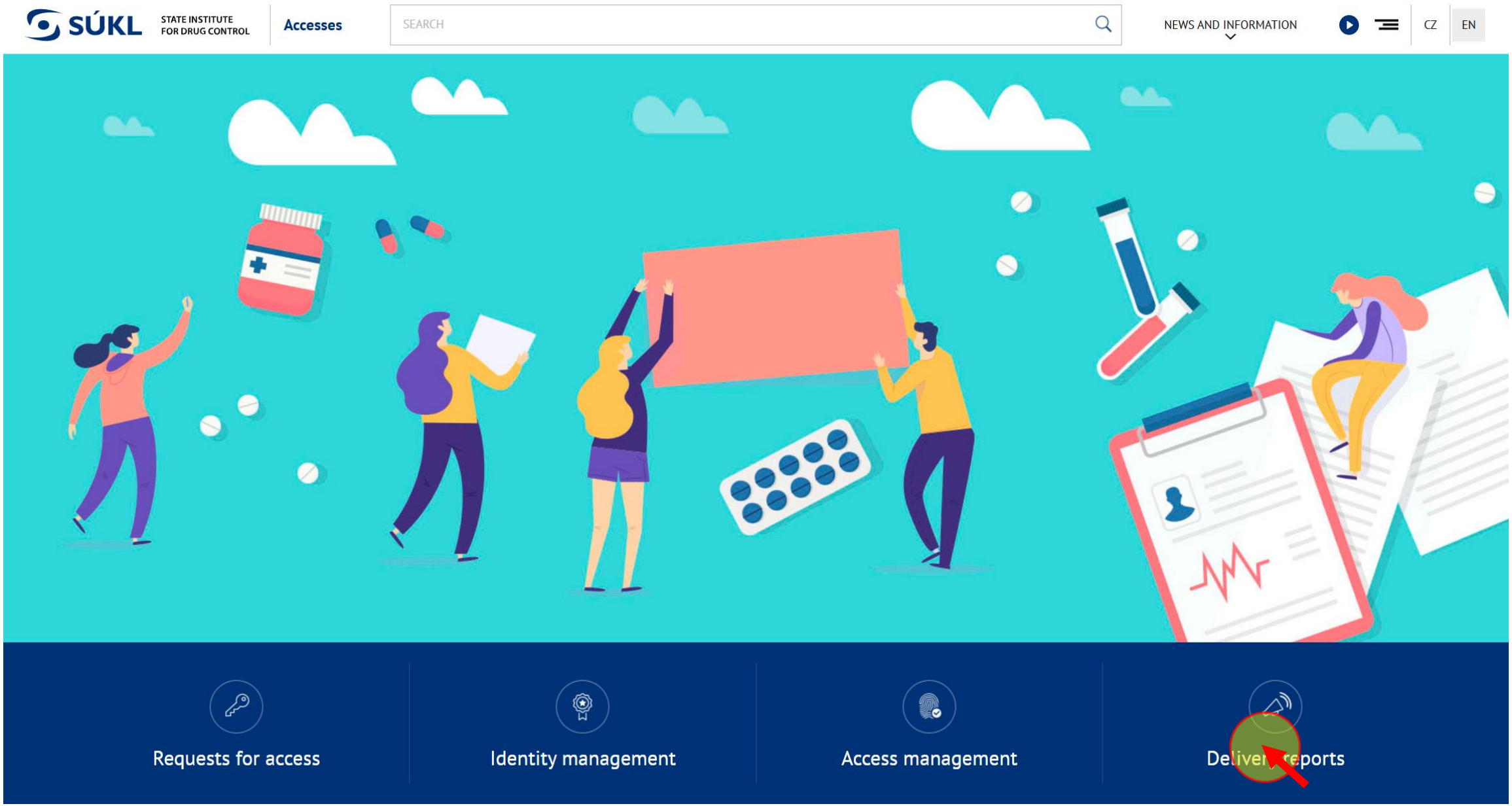
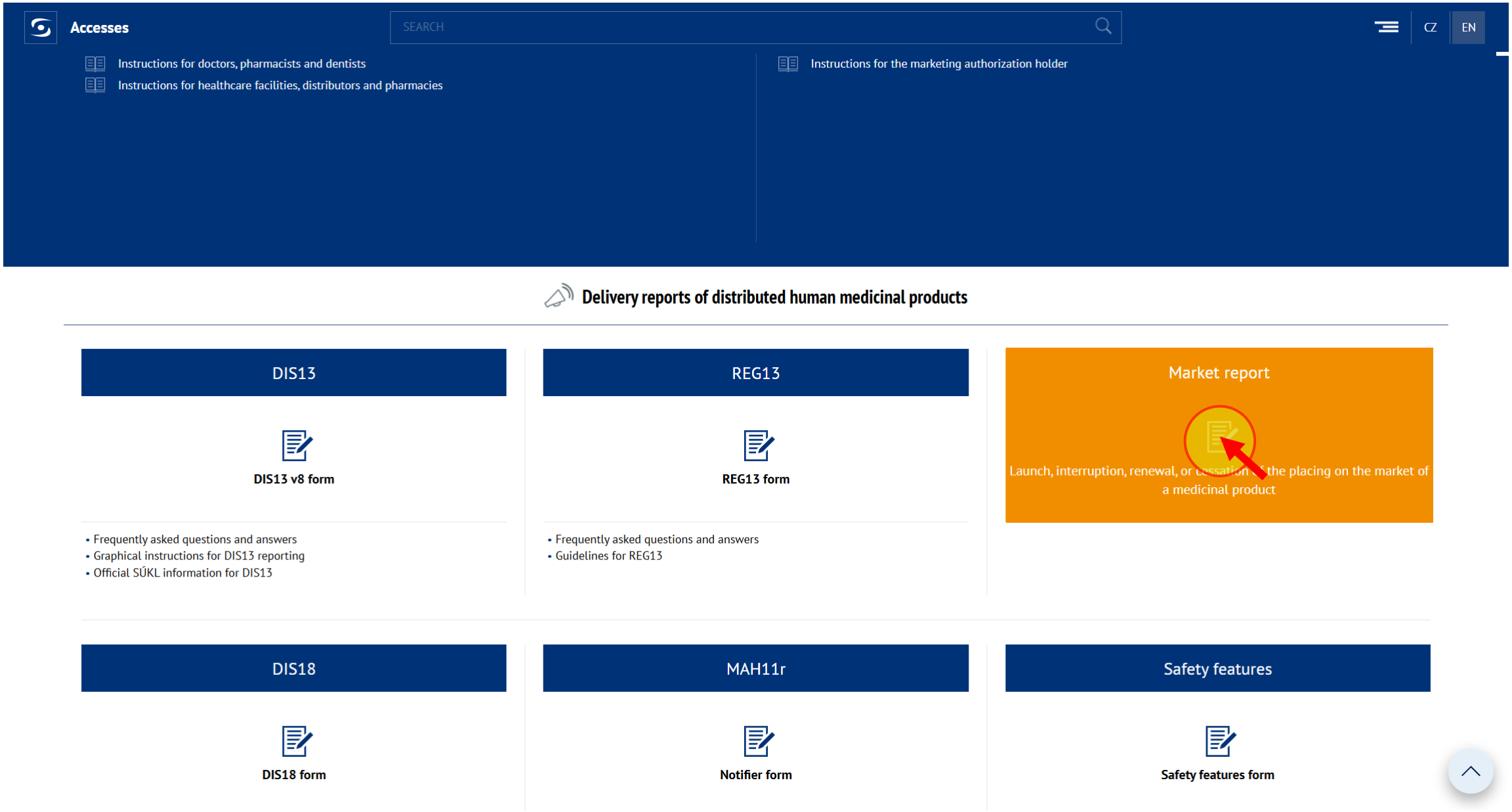
Reporting of the launch, interruption, renewal or cessation of the placing on the market of a medicinal product

Instructions for Using the Application

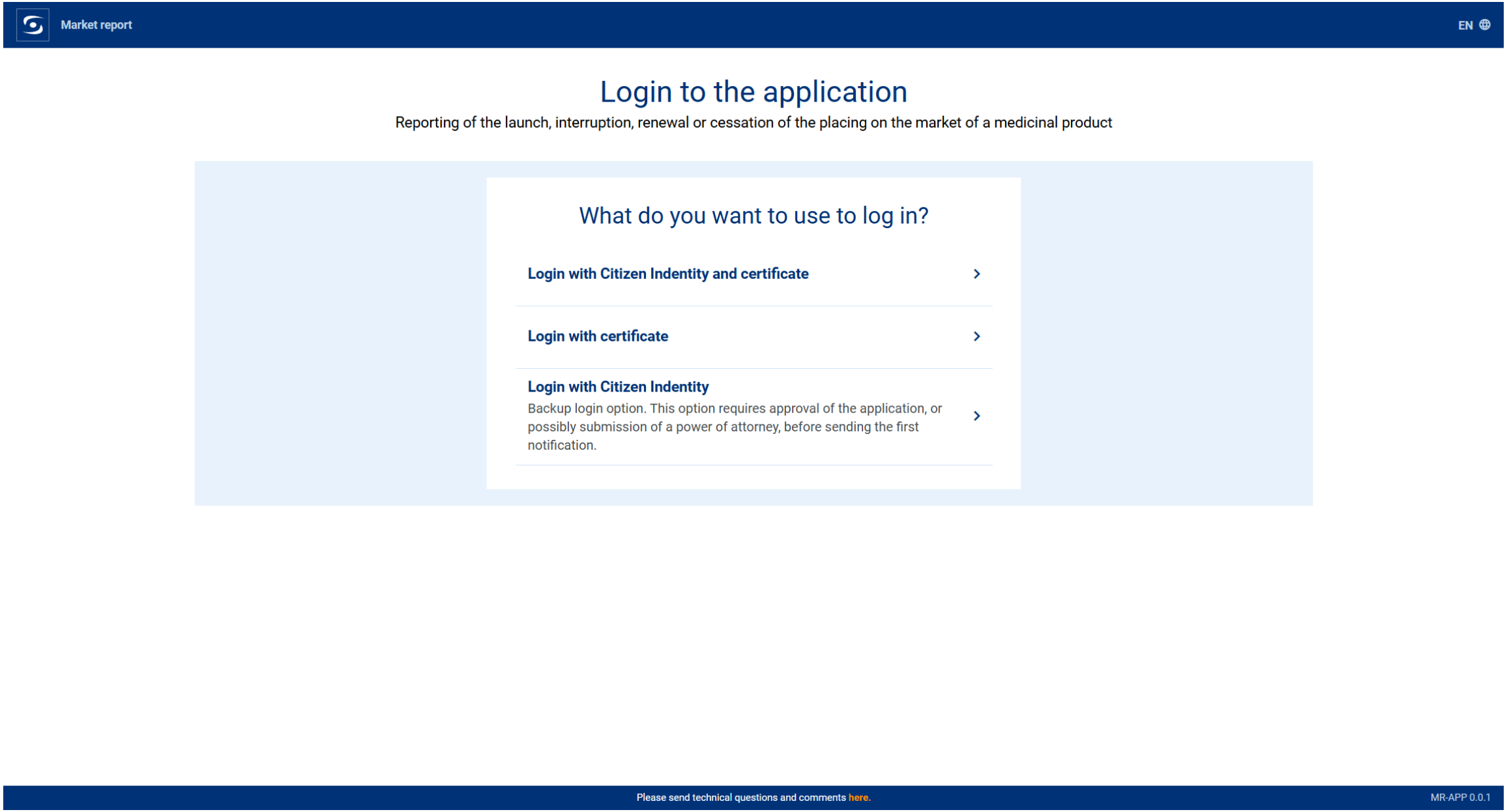
1. On the website SÚKL Accesses, select “Delivery reports.”



2. Among the reports, choose ”Market report - Launch, interruption, renewal, or cessation of the placing on the market of a medicinal product. ”

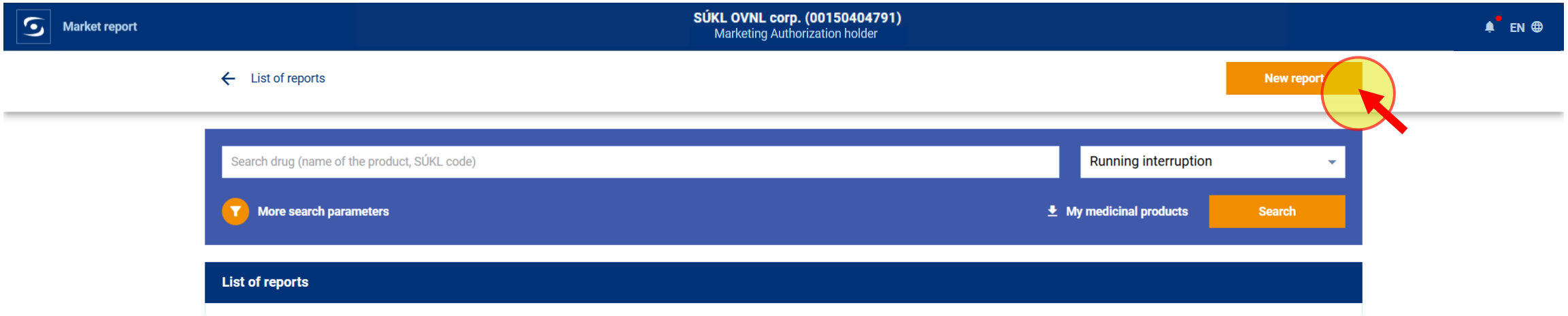


3. Access to the application is possible via Citizen identity with a certificate, via certificate only, or via a third backup option.

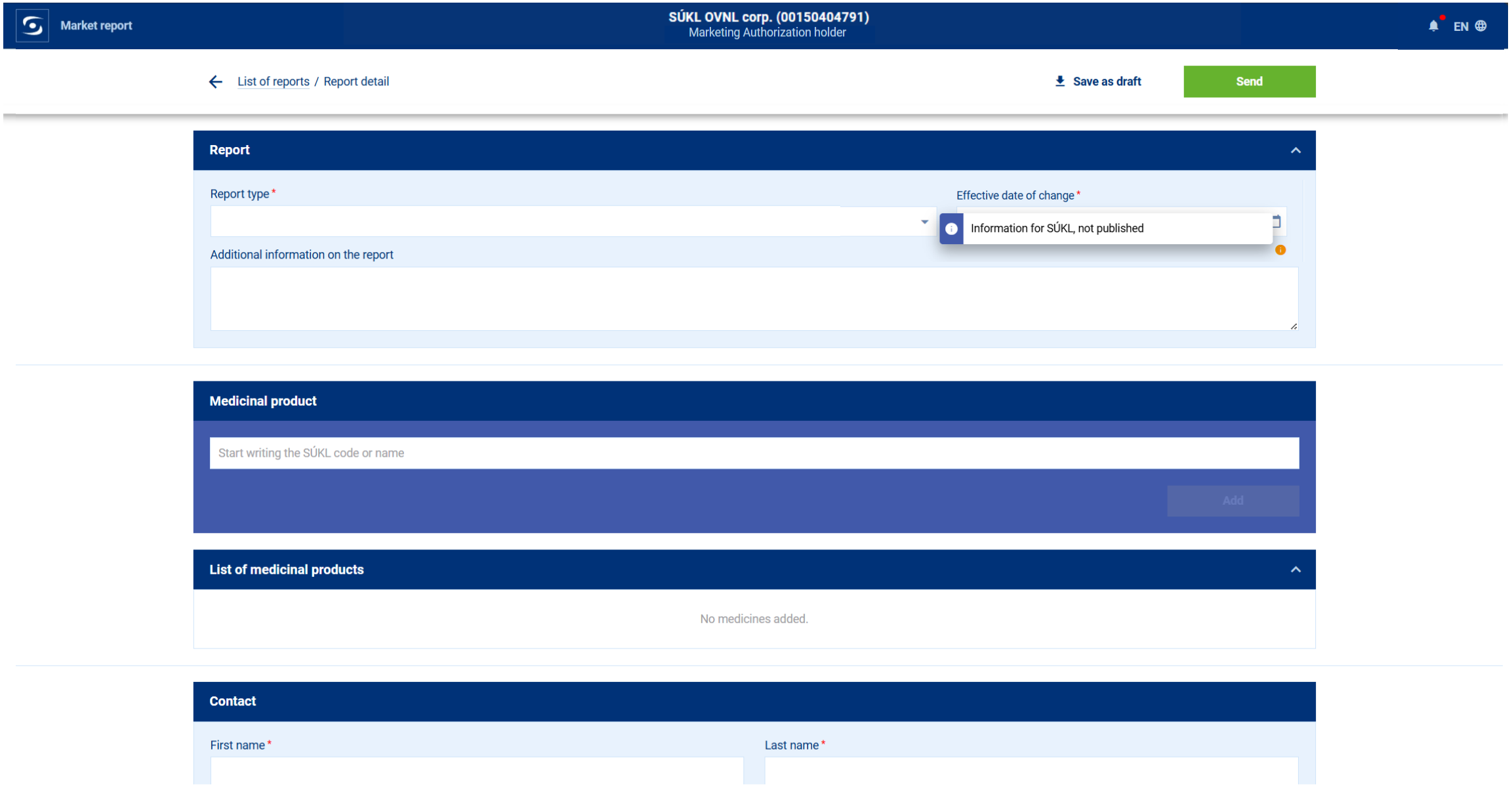


Submission of a new report

4. To submit a new report regarding launch, interruption, renewal, or cessation of marketing, click the “New report” button.

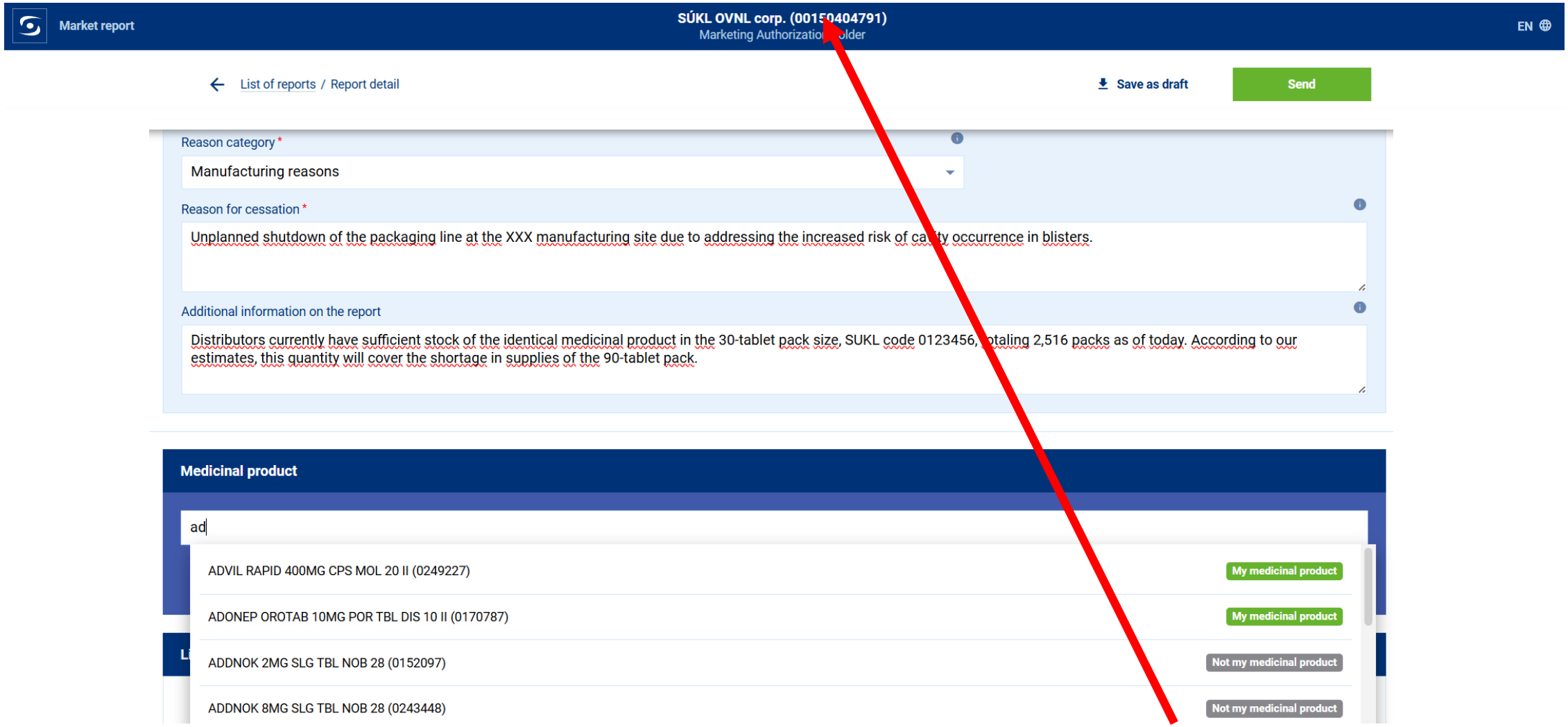


5. Mandatory fields are marked with an asterisk. The explanation indicates whether the information is intended for publication or only for SÚKL's internal use.



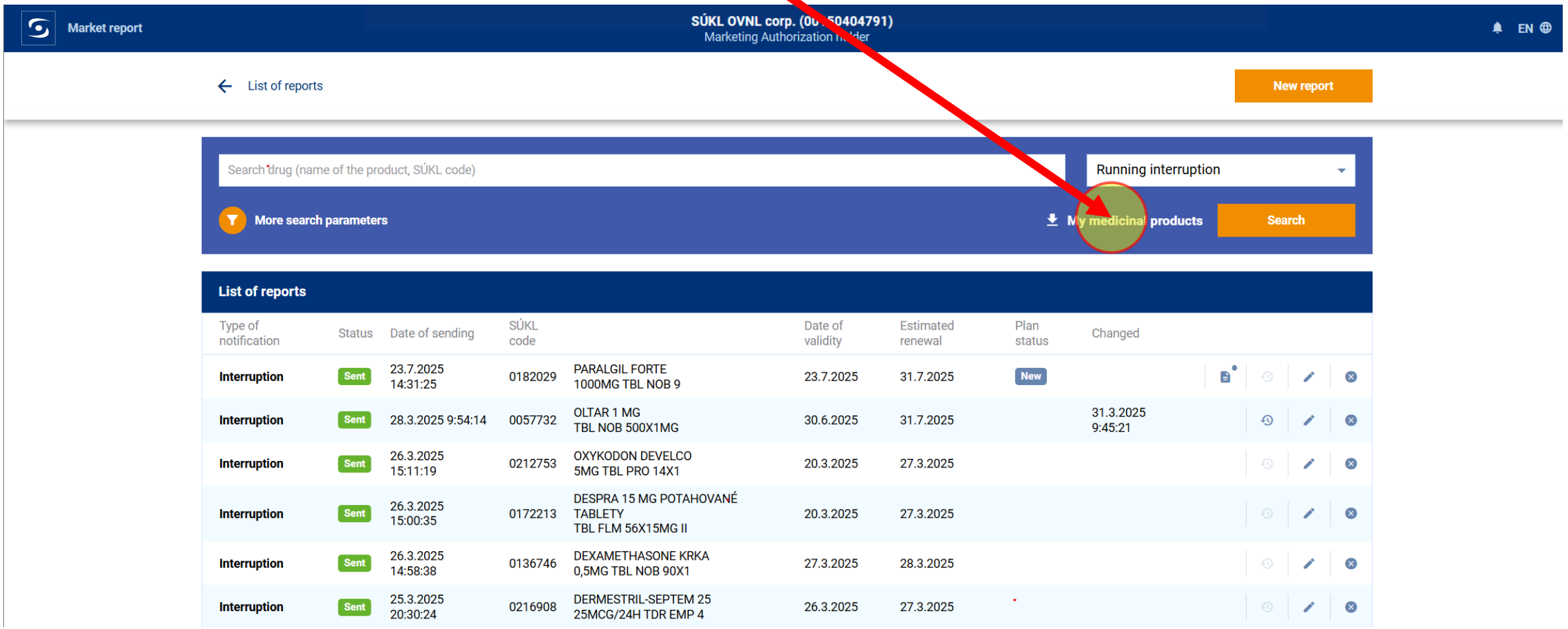
6. Select the type of report and the date from which the change in marketing will take effect.

7. In the “Medicinal product” section, add the medicinal product concerned. The autocomplete feature distinguishes between products that can be reported under the current login (“My medicinal product”) and those that cannot (“Not my medicinal product”).



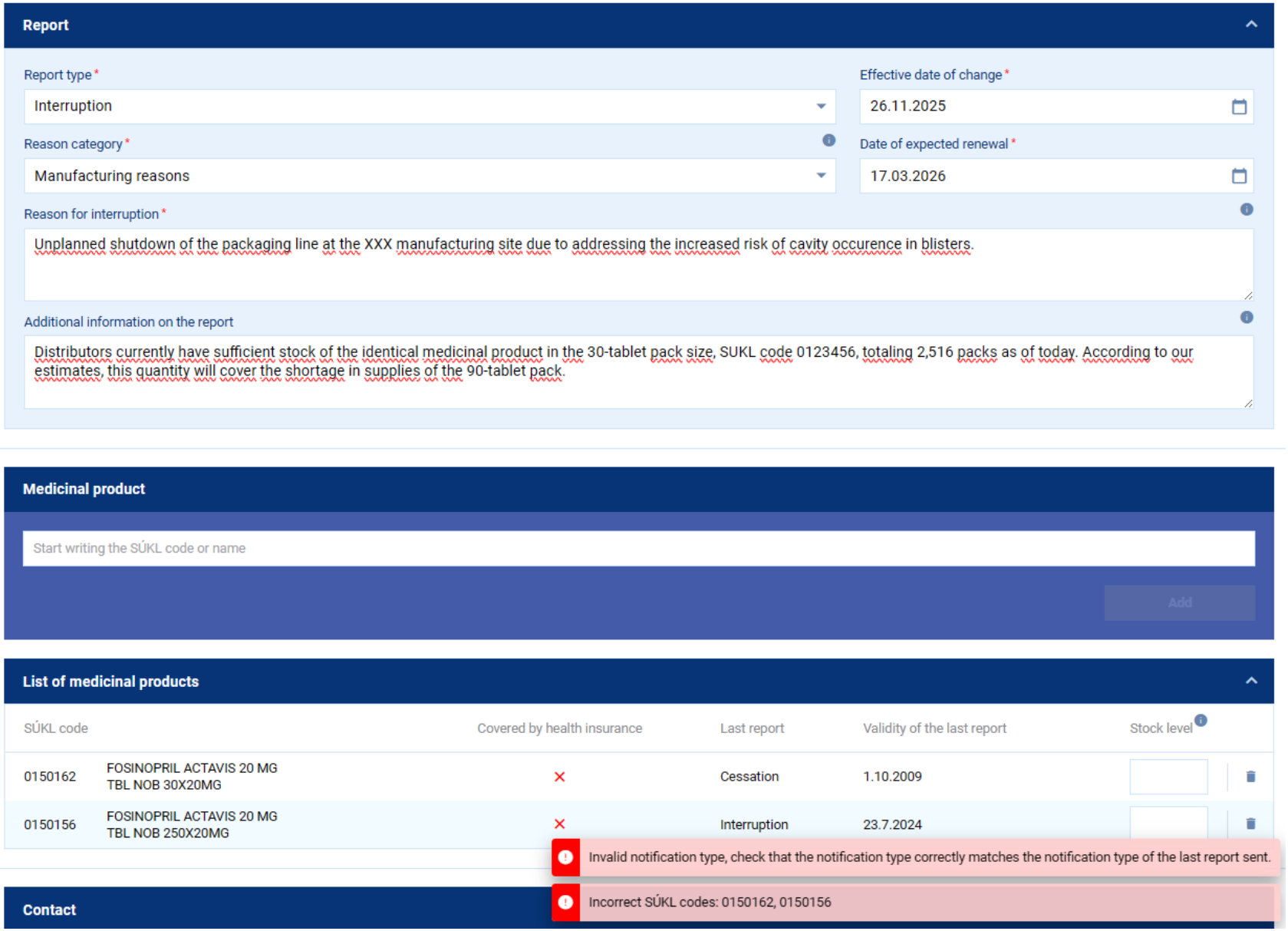
The application allows reporting only for products of the holder identified by the workplace code shown in the application header.

8. From the main page of the application, you can download a list of all your products in XLS format using the “My medicinal products” button.

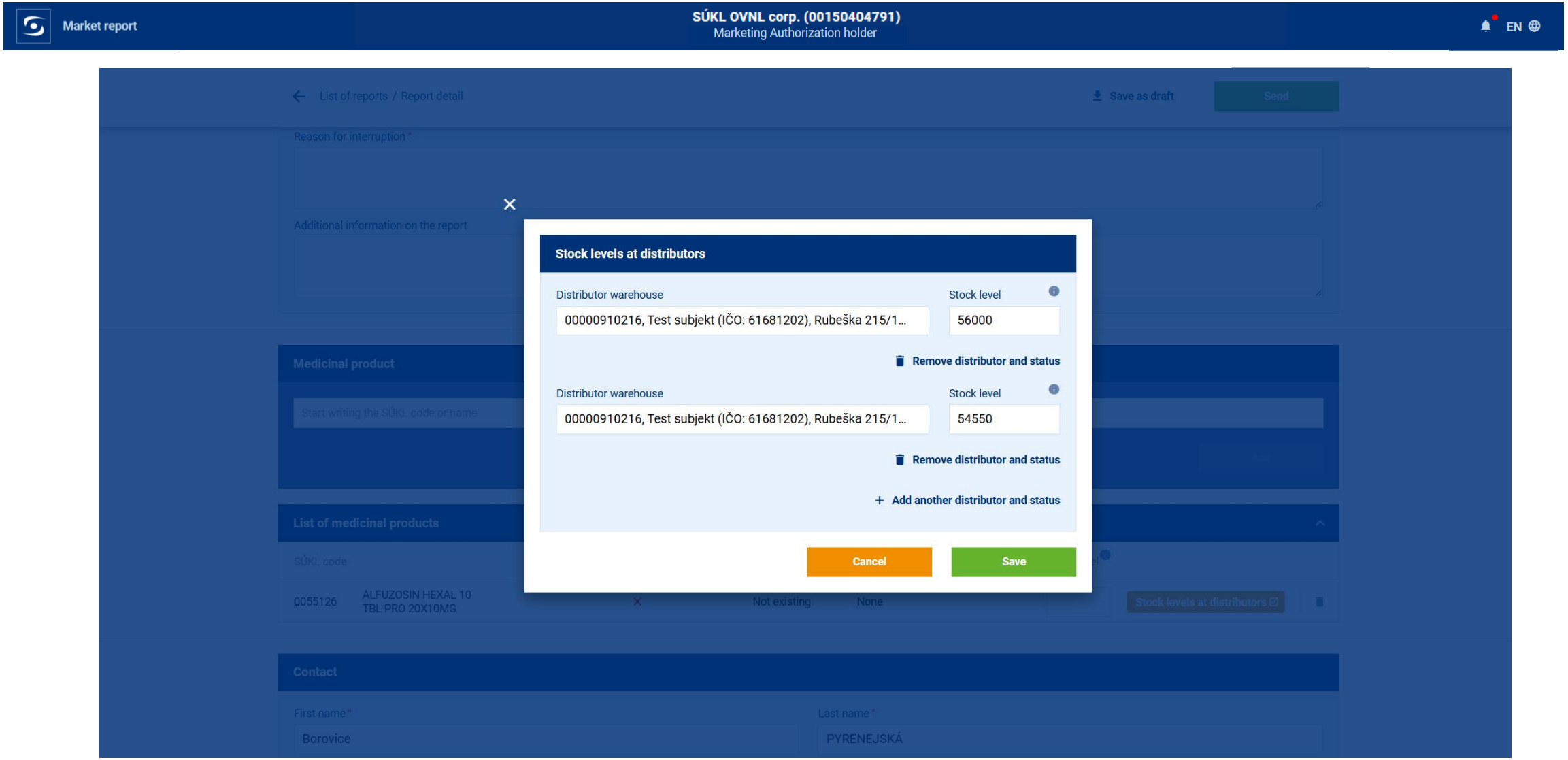


9. After adding, the medicinal products appear in the list, including data from the last report. The application does not allow sending two reports of the same type consecutively or logically inconsistent reports.

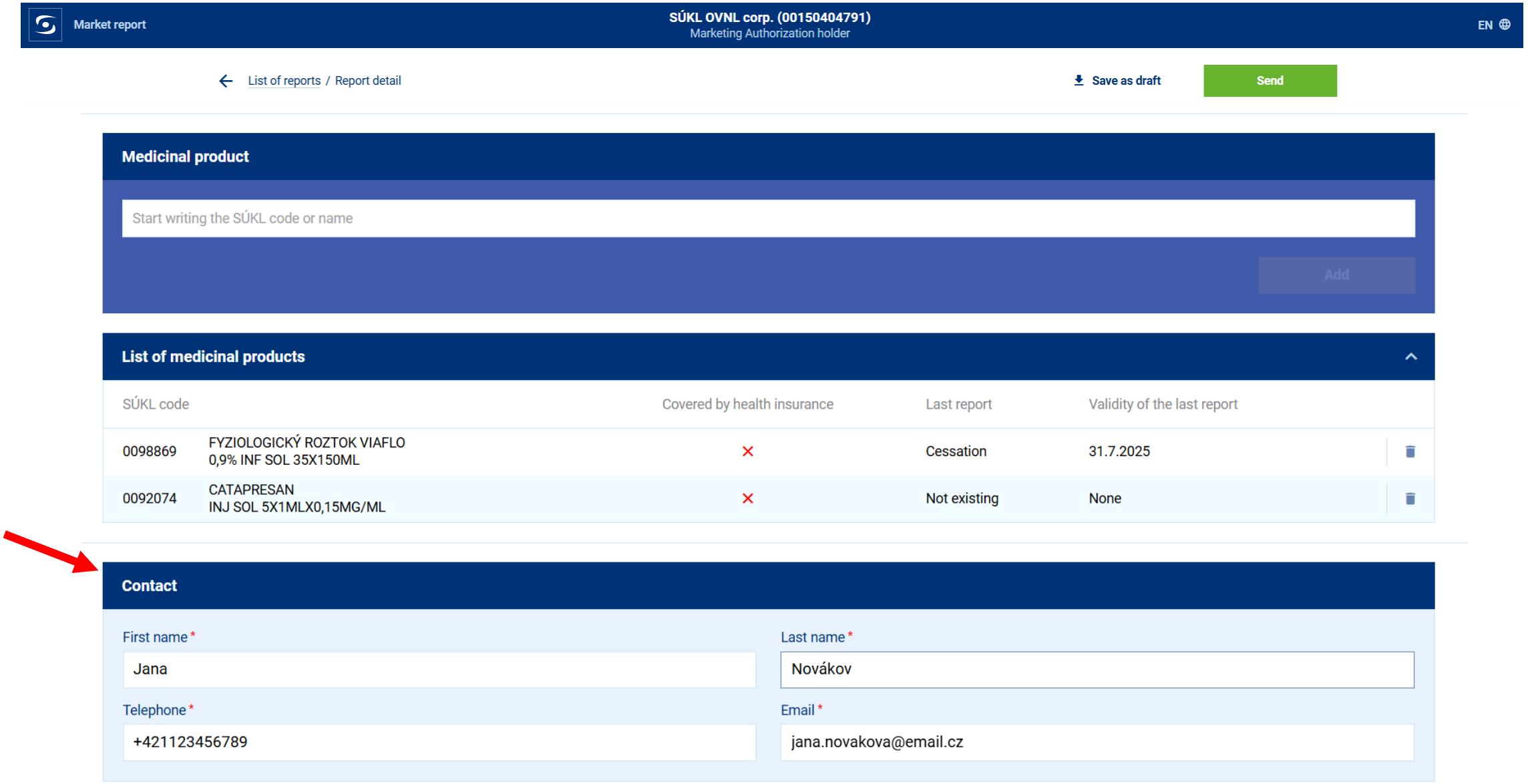
For example, after an interruption, it is not possible to send a launch report, only a renewal or final cessation. Similarly, it is not possible to send a report for a product that already has a future-dated report. Such reports can be edited or canceled from the List of reports. In the case of interruption, it is mandatory to state the stock level within the sphere of influence of the marketing authorization holder.



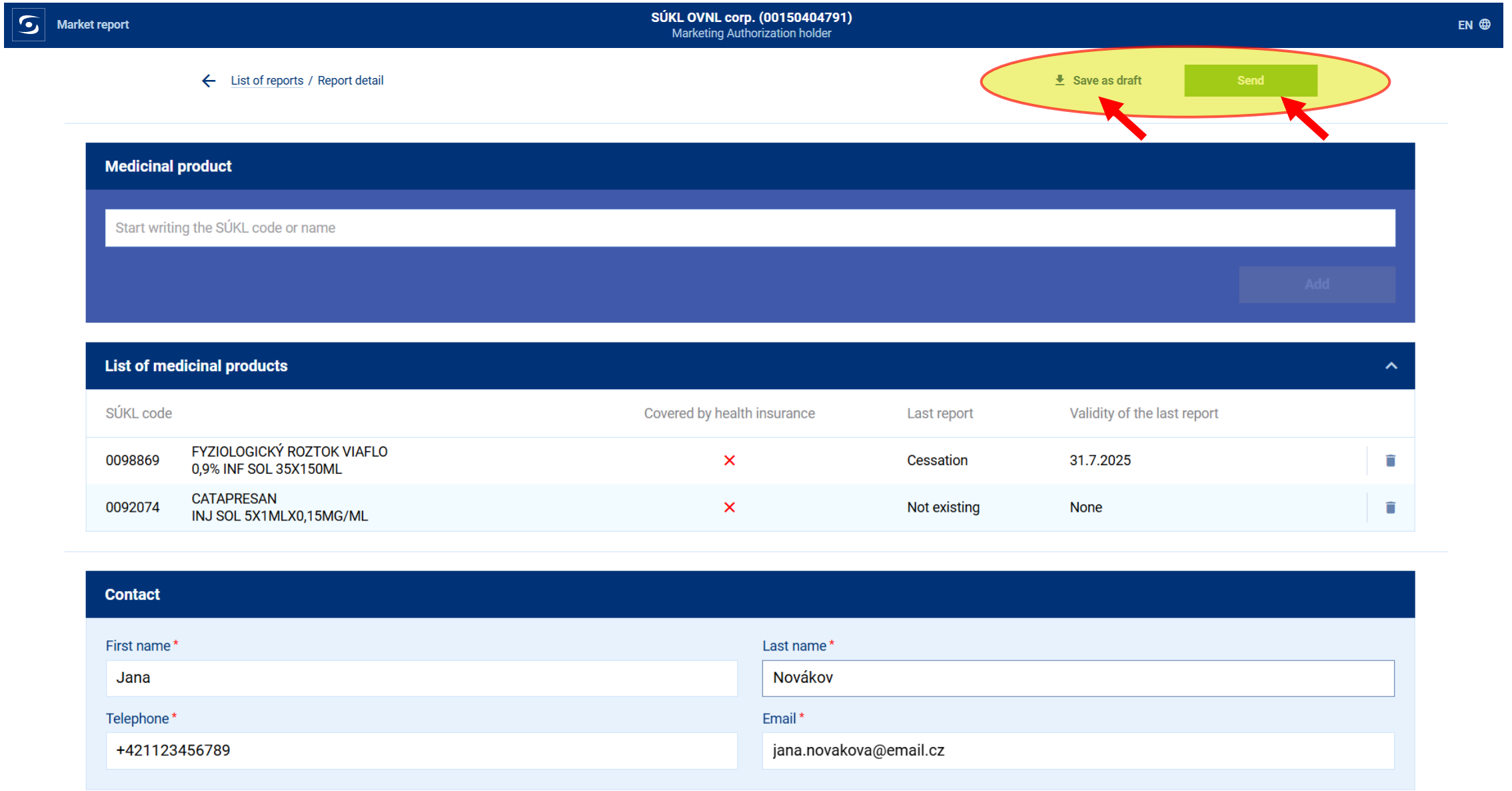
10. For the report type “Interruption without publication,” it is also mandatory to state the stock level within the sphere of influence of the holder, broken down by individual distributors. A distributor within the influence is only a distributor whose distribution can be affected by the marketing authorization holder.



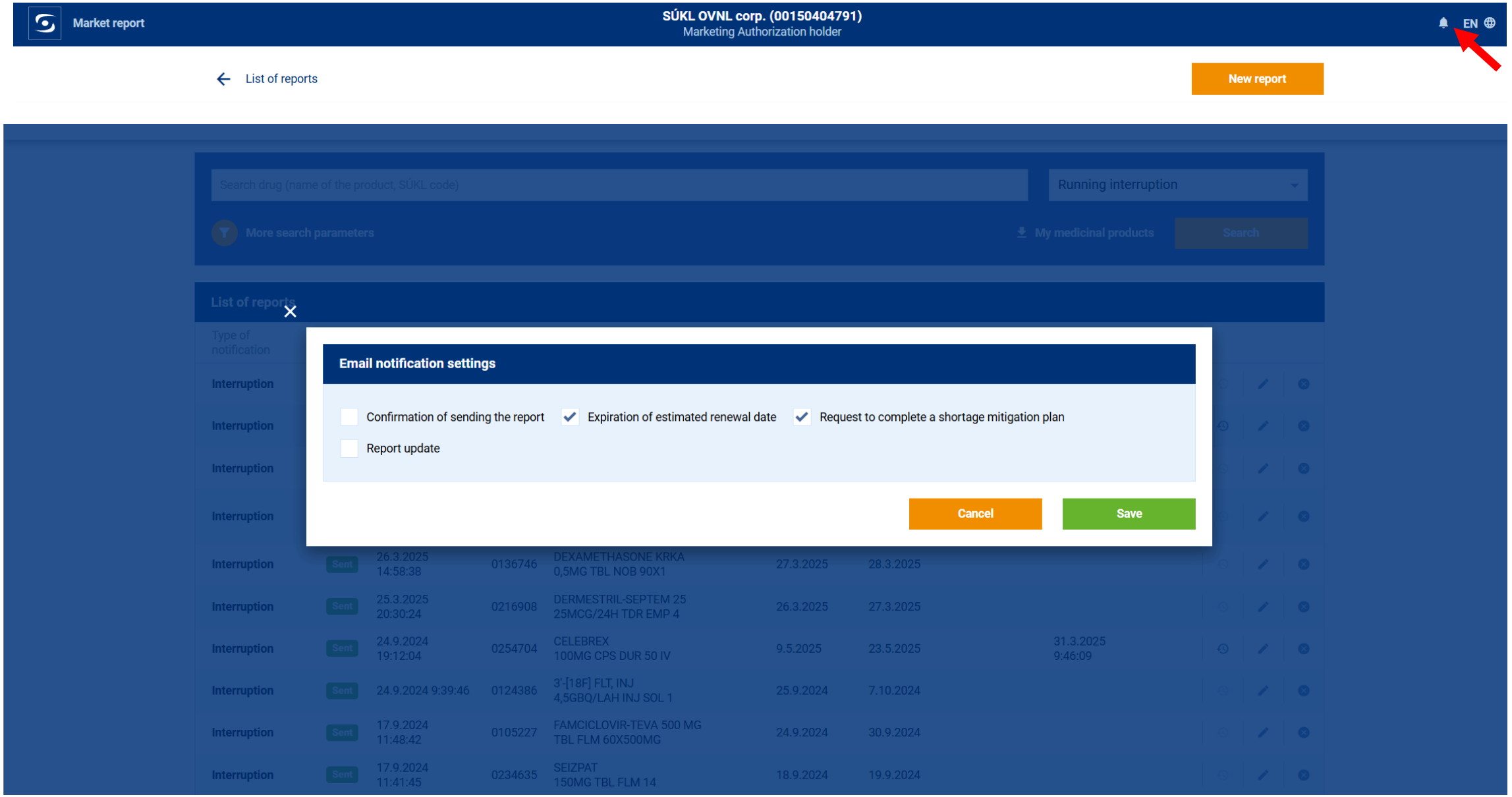
11. The “Contact” section displays contact details based on the last entered data. If necessary, they can be overwritten with new data.



12. A correctly filled report can be saved as a draft or sent immediately.

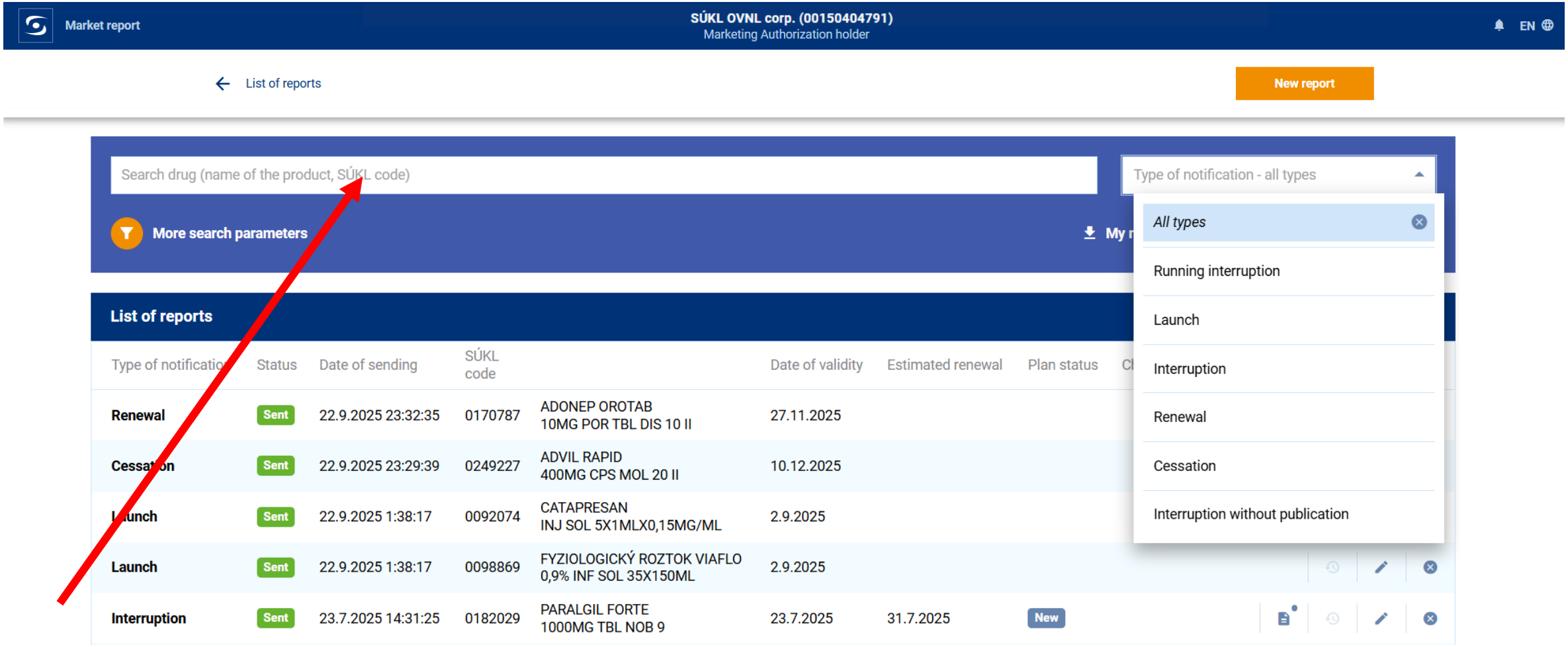


13. You will receive email notifications according to your settings at the email address entered in the “Contact” section under the bell icon located on the main screen.



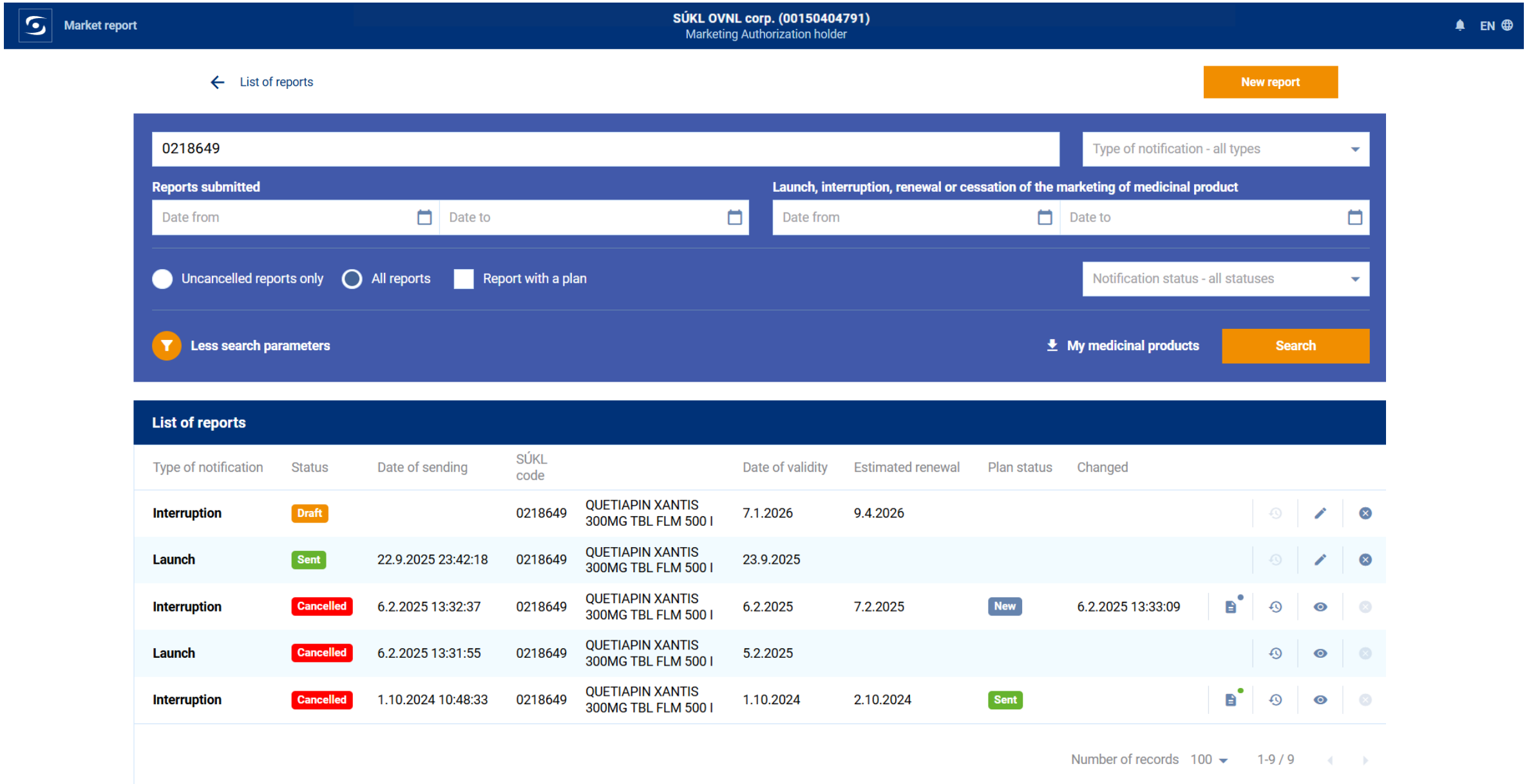
List of Reports

14. By default, only your currently valid running interruptions are displayed in the report list. The dropdown menu on the right allows filtering by report types or displaying all submitted reports.



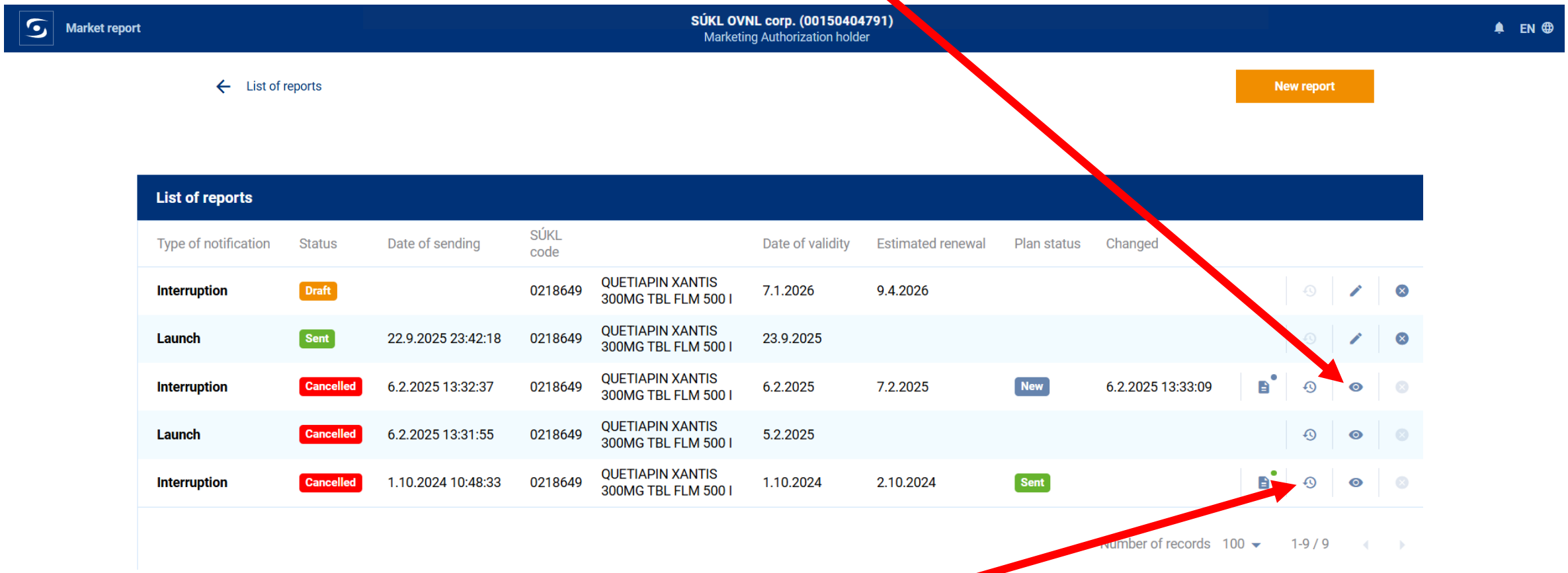
The filter also allows searching by product name or SÚKL code.

15. After displaying more search parameters, additional details can be used for filtering, e.g., showing draft reports that have not yet been sent.



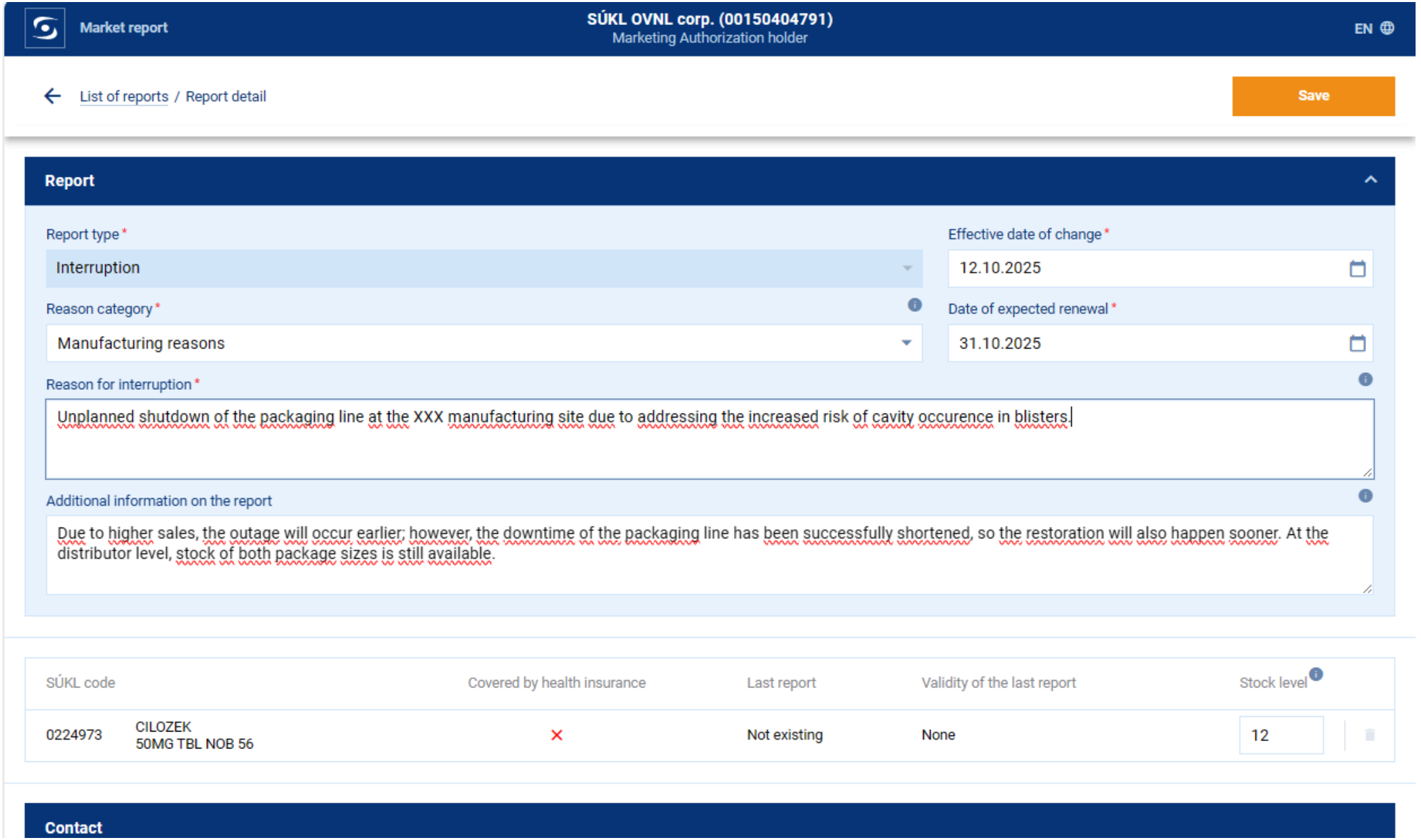
Editing and Canceling Reports

16. Only the last valid report for a specific product variant identified by the SÚKL code can be edited or canceled. Previous reports can only be viewed in detail (eye icon).

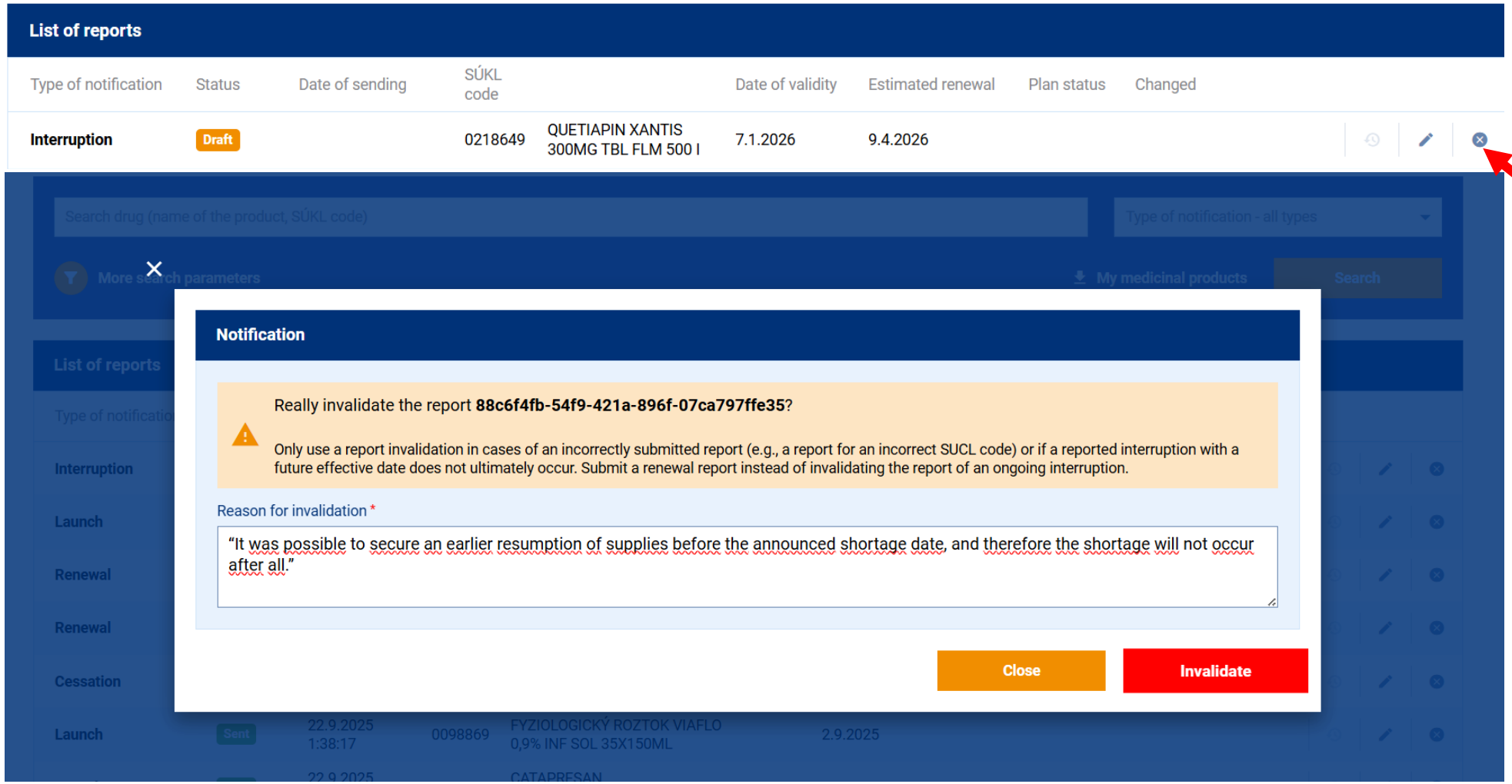


If the report was edited, you can view the edit history (clock icon).

17. Editing is mainly used when the expected date of renewal needs to be changed or the future interruption date updated.



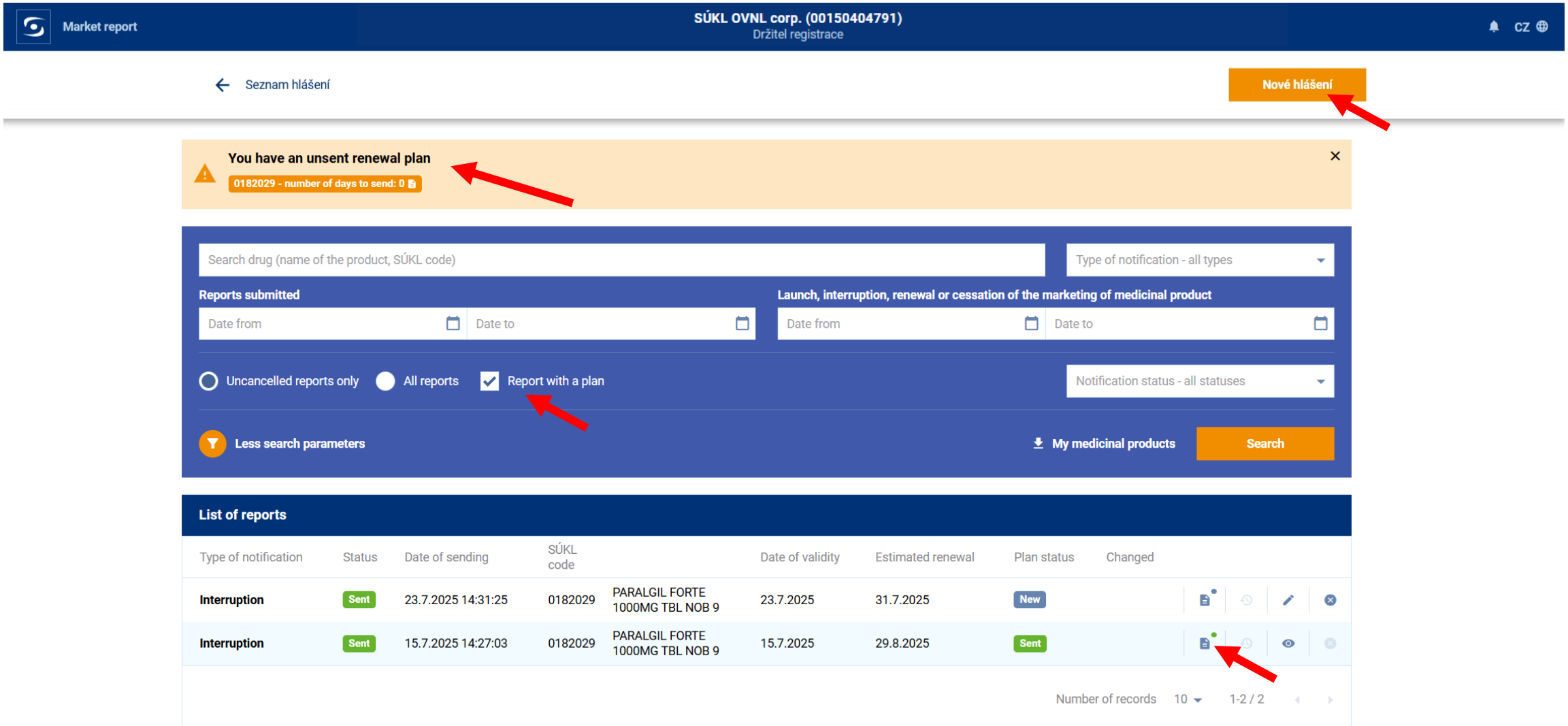
18. When canceling a report (cross icon), the reason for invalidating the report is required. This reason is not public and is intended only for SÚKL.

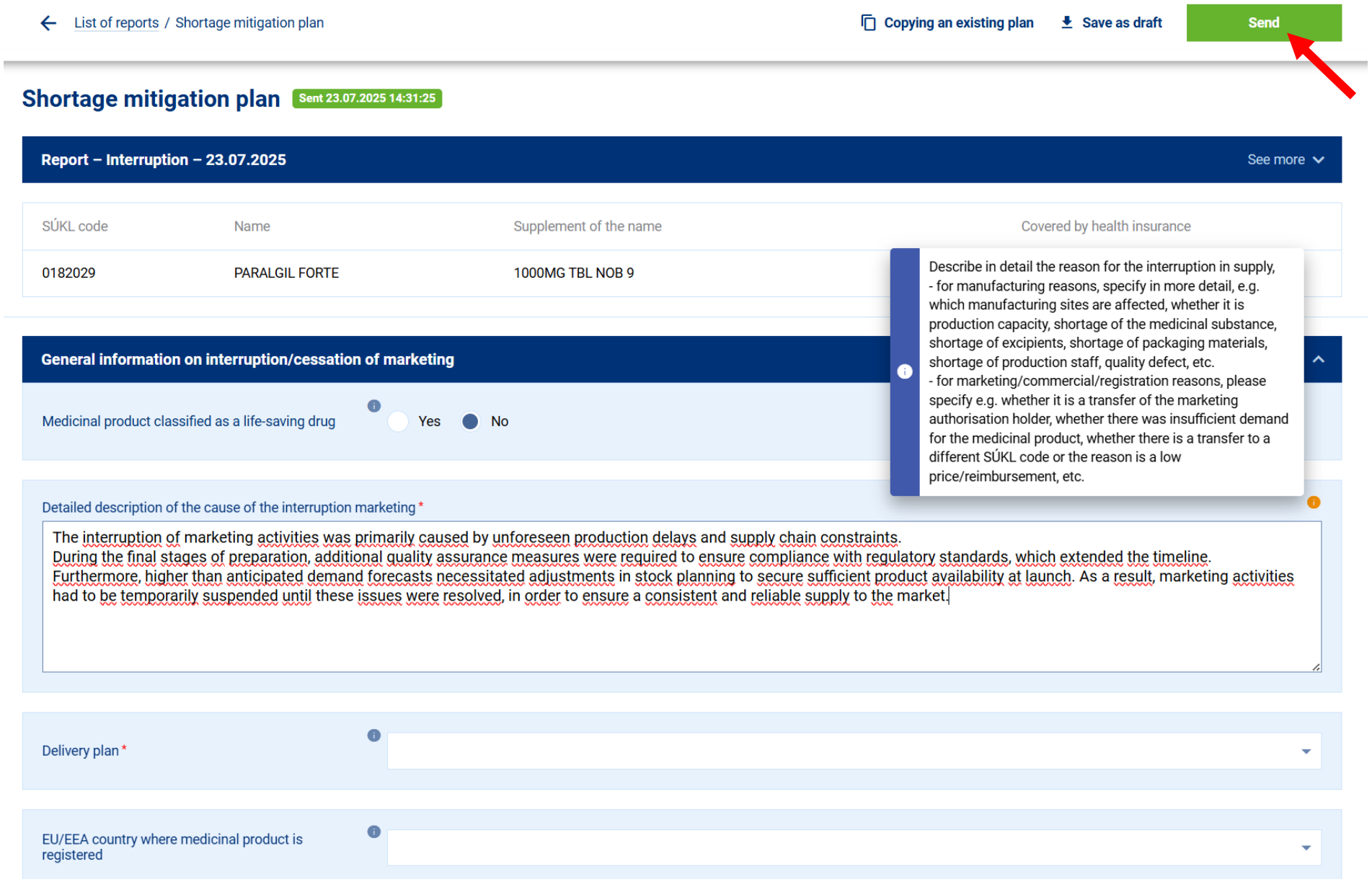


Important: If the medicinal product becomes available again after a shortage, do not cancel the interruption report, but submit a new report of renewal.

Shortage Mitigation Plan

19. If the holder is required to supplement the Interruption report for a product marked “limited availability,” a report email will be sent requiring completion of the Shortage Mitigation Plan.



All requests for completing the Shortage Mitigation Plan can be viewed in the List of reports by checking the “Report with a plan” option. In the “Plan Status” column, statuses such as New, Draft, and Sent are available. The plan details are shown by clicking the icon.

20. In a new or draft plan, you can copy data from another draft or saved plan using the “Copying an existing plan” function. After editing, don’t forget to save or send the plan.