24/02/2025

Urgent Field Safety Notice

Dear Customers,

DH Healthcare GmbH, a Dedalus Group company, would like to bring to your attention the following issue reported to the national competent authority:

Title: Display of an English message instead of the administration condition when cancelling the pharmaceutical validation of a conditional prescription

Internal Reference: MST0096007

Product name and version(s) and UDI-DI:

- ORBIS Medication 03.20.00.00 in ORBIS 84.42.00.00, 85.25.00.00 and higher in Germany, Austria, Switzerland, Luxembourg, and France - Manufacturer: DH Healthcare GmbH
  UDI-DI: 4260693990026

Information:

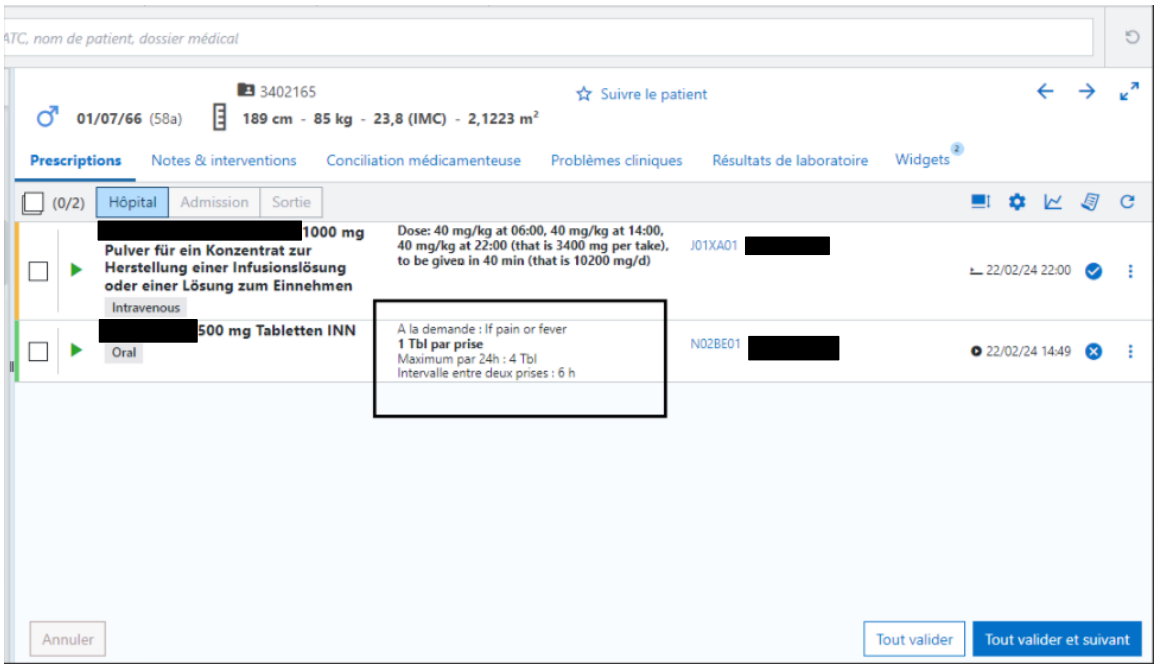
Only relevant for customers who use the pharmaceutical validation process of prescription lines in ORBIS Medication.

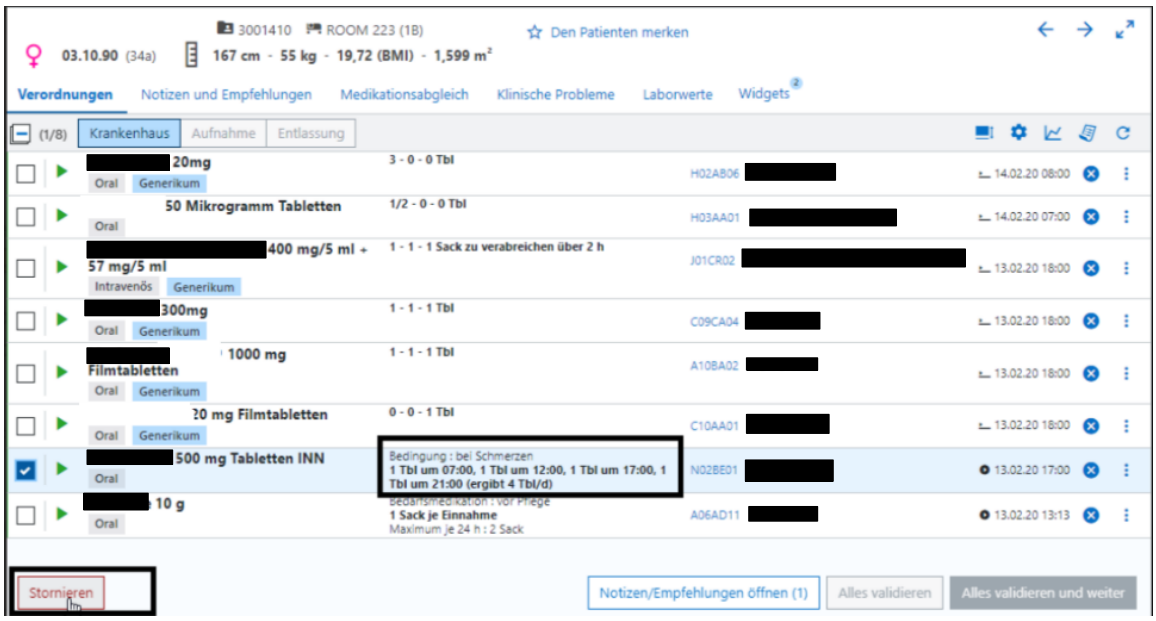
After updating to ORBIS Medication version 03.20.00.00 included in ORBIS 08.42.00.00, the following behavior occurs:

In the drug prescription list, as well as in the patient chart (summary section and administration screen), the English text “The condition is not determined and so not supposed to be used for display” is displayed instead of the condition for the prescription line with conditions (e.g. on-demand medication, PRN, schema, unknown dosage).

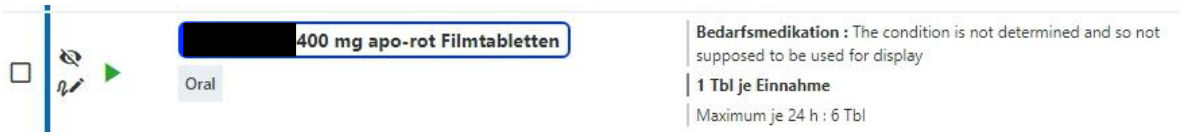
This behavior only occurs if a condition was entered as part of the prescription, the prescription was then signed, validated by the pharmacist and then unvalidated using the cancel action (e.g. via the pharmacy workplace).
As long as the pharmaceutical validation has not been cancelled in the pharmacy workplace, the display in the drug prescription list and in the patient chart is correct.

Example of display of the condition in the pharmacy workplace before the cancel of the pharmaceutical validation:

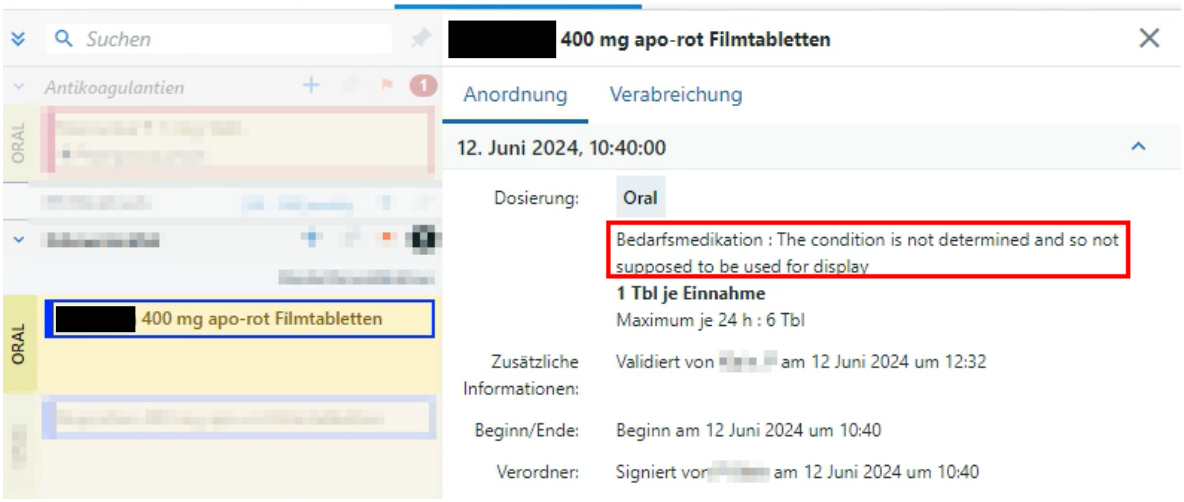




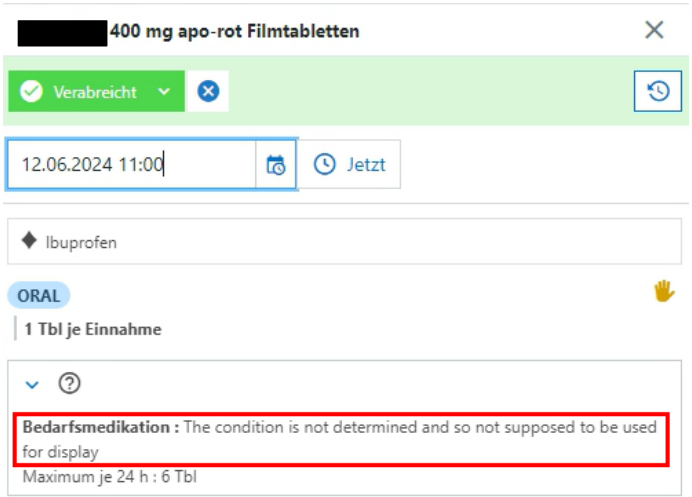
Example of display of the condition in the drug prescription list after the cancel of the pharmaceutical validation:

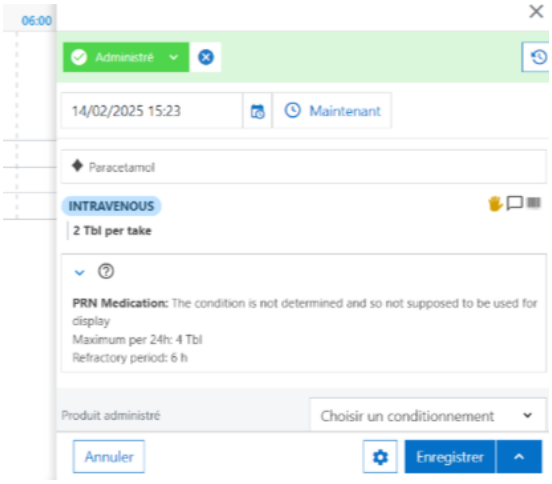


Example of display of the condition in the summary in the patient chart after the cancel of the pharmaceutical validation:



Example of display of the condition in the administration screen in the patient chart after the cancel of pharmaceutical validation action:

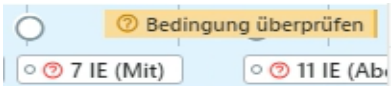




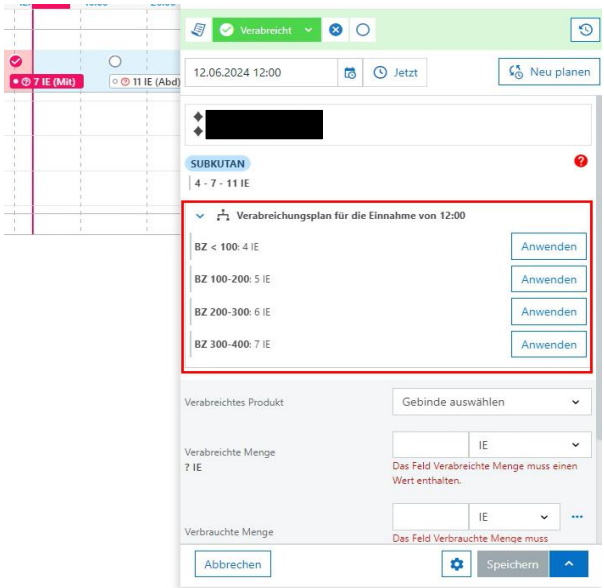
After the cancel of the pharmaceutical validation, there is a display issue for the prescription lines with a schema in the patient chart. Instead of the symbol for a schema, a dosage is displayed.

Before validation is done:

After cancel of validation is done:



The schema is presented correctly when clicking on an administration:



Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.

Release of correction with ORBIS Medication version 03.20.05.00 or higher in ORBIS version 84.42.08.00 DACHL or higher (release planned for March 2025) in ORBIS version 84.43.00 FR or higher (release planned for Q4 2025) and in ORBIS version 85.26.00 FR or higher (release planned for June 2025)

Recommended actions to be taken by the customer:

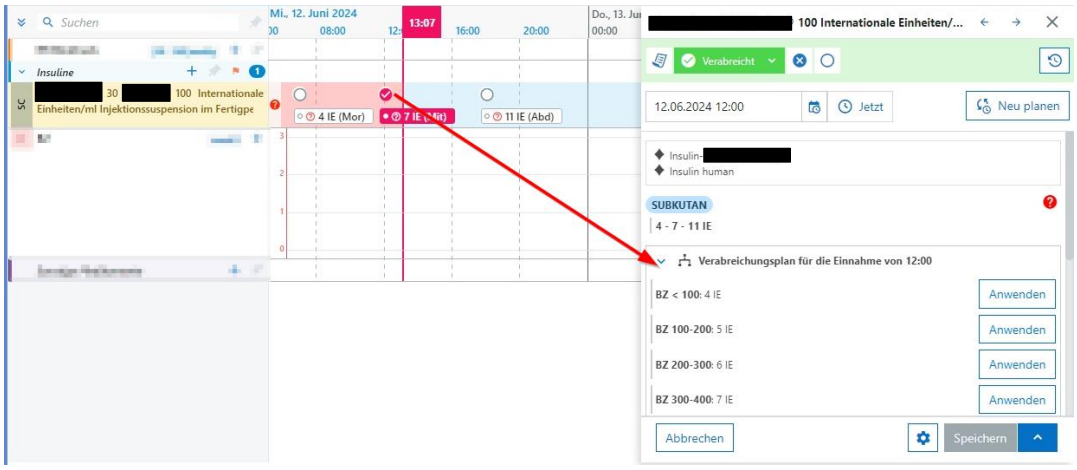
If the pharmaceutical validation workflow is used in the hospital:

- As a pharmacist: Don't cancel pharmaceutical validation for prescriptions with conditions until the correction is installed and add a pharmaceutical advice on this prescription line to inform the other healthcare providers.

- As a physician: Check the active prescription lines of patient cases and change them if an entry in the order summary is incorrect. To do this, you can edit the prescription and sign it again without making any changes. The condition will then be displayed correctly again.

- As a nurse: If the English text "The condition is not determined and so not supposed to be used for display" is displayed for the condition in the order line summary or if other data is not displayed correctly, please contact the doctor and ask them to edit the line.

- As a nurse: If you are about to administer a drug with a schema, make sure to open the administration and check the schema in the administration view before administering the drug.



- The transfer to the discharge medication and to the discharge letter takes place with the correct representation of the condition.

Please distribute this information to all those who need to be aware of it and confirm the acknowledgement by sending the signed response form.

Regardless of the situation described here, we would like to point out that care providers must always ensure that clinically relevant information, including prescription information, is clearly communicated and that they must use verified information (e.g., from medical devices such as monitoring systems), independent from the software being used.

It is important that you take the actions described in this safety information and acknowledge receipt of this letter.

If the above information does not apply to your hospital or if the device has been transferred to another organization, please indicate this on the attached feedback form and forward this Field Safety Notice to the respective organization.

Thank you for your careful attention to this matter and for your support.

If you have any questions on this matter, please consult our contact person:

Sincerely,

Urgent Field Safety Notice

Feedback Form

We kindly ask you to return this feedback form as soon as possible, but at the latest **within 30 days** after receipt of this letter, to the following e-mail address:
Thank you for your cooperation.

Customer / Facility (names of all affected operational facilities):	
Address:	
Reference	MST0096007: Display of an English message instead of the administration condition when cancelling the pharmaceutical validation of a conditional prescription
Product reference:	ORBIS Medication
Name (contact person)	
Position	
Phone number	
Date	
Signature	

☐ I confirm that I have received and understood the safety information.

☐ The safety information does not apply to my facility.

☐ The device was transferred to another organization.

Name and address of the other organization: _____

☐ Please update our contact information as follows:

Customer / Facility:

Address: