29.04.2026

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: Frequency of prescriptions defaults to "daily" if not specified in a structured way in the import source

Internal Reference: MST0110540

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

ORBIS Medication 03.21.01.02 ORBIS version 84.43.02.00 and higher in Germany and Austria,
Manufacturer: DH Healthcare GmbH
UDI-DI: 4260693990026

Information:

The following issue occurs when importing prescriptions without structured dosage information from external sources (i.e. Bundesmedikationplan in Germany or ELGA Medication in Austria) into ORBIS Medication.

The external source could include a prescription with a free text dosage instructions (non-structured format), which may include an administration frequency described within the free text comment (e.g., weekly administration). When the dosage or the frequency information is not provided in a structured way during the import process in ORBIS Medication the physician must transfer this information manually to the prescription line in ORBIS Medication before signing. However, during this editing, the user must enter the dosage information in the corresponding prescription instructions field, while the system automatically presents an editable default frequency as “daily” in the corresponding field.

If this is overlooked, and the user does not perform the manual action to change, the structured frequency field remains to the default daily schedule, even though the intended frequency may be described differently within the free text comment.

Example of scenario leading to this issue:

- A prescription from an external source (e.g. Bundesmedikationsplan in Germany or ELGA Medication in Austria) is imported into ORBIS Medication. The prescription instructions are not structured and the dosage instructions, including the frequency, are displayed as a free text.

Wirkstoff	Handelsname	Stärke	Form	morgens mittags abends zur Nacht	Einheit	Hinweise	Grund
Alendronsäure	Alendronsäure [redacted]70&& mg Tabletten	70 mg	Tabl	siehe Hinweistext	Tbl	1 Tbl um 06:30, alle 7 Tage	
Methotrexat	[redacted] FS 25 mg&& Injektionslösung in einer ...	25 mg/ml	Injekt	siehe Hinweistext	Stück	0,5 Stk um 10:00, alle 14 Tage	

- This prescription is imported (Figure 1) into ORBIS Medication Admission List as a simplified prescription (Figure 2). The intended administration schedule (e.g., once weekly) is described within the free text comment.

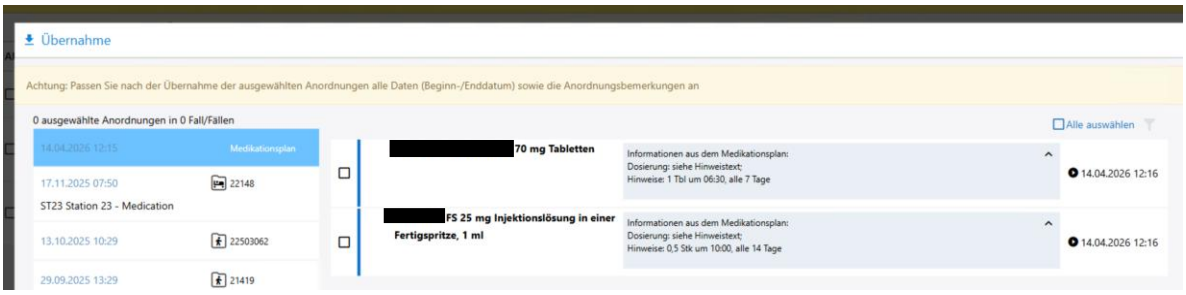

Figure 1: Import from an external source in ORBIS Medication

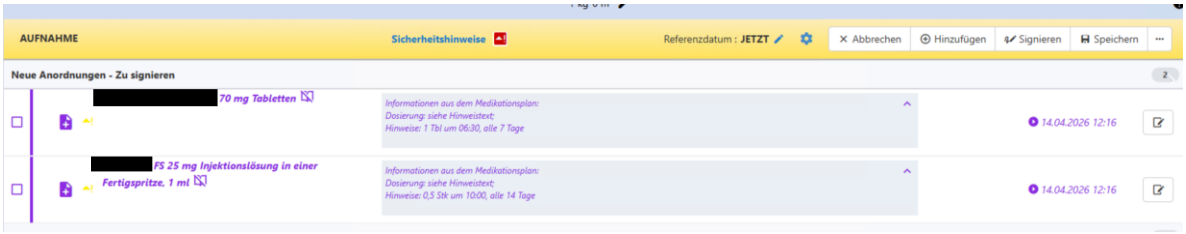

Figure 2: Display of a simplified prescription in the ORBIS Medication Admission List

- A physician accesses the admission prescription screen and imports this prescription line into the hospital prescription (Figure 3).

Figure 3: Display of a simplified prescription in the ORBIS Medication after takeover into hospital

- Because the dosage is not imported from a structured field, the prescription line is marked as incomplete (shown in red) (Figure 3). To complete it, the user must edit the prescription and enter the missing information. When the user opens the prescription instructions (Figure 4), the screen shows default values: the dosage is empty and the frequency is set to daily. A comment “Anordnungsbemerkung” at the top shows the additional information from the external source to guide the user when entering the dosage instructions.

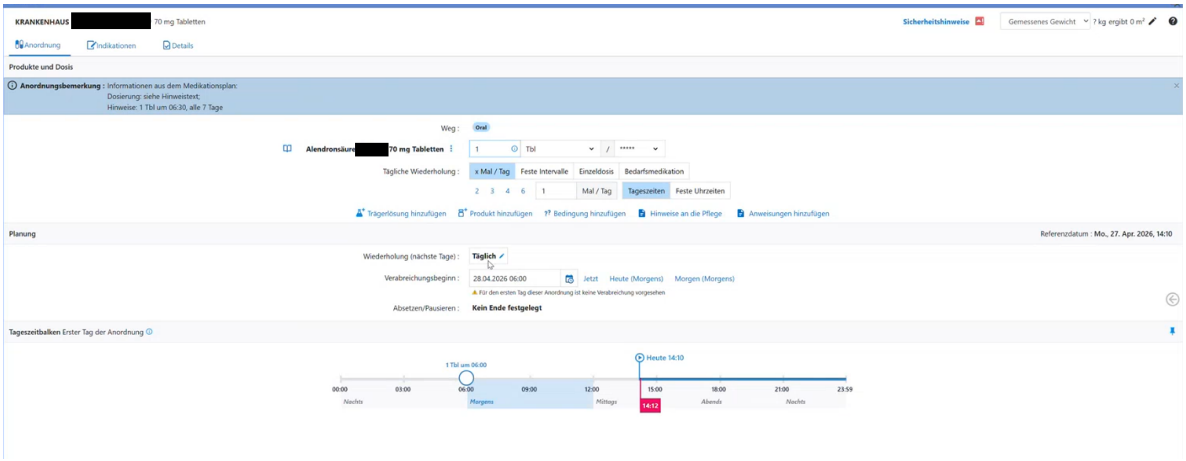

Figure 4: Prescription instruction screen, with the information of the unstructured dosage and frequency

If it is not review and adjust the default values in the prescription instructions screen during editing, the system's prefilled frequency ("daily") may remain unchanged and create a discrepancy between the intended prescription schedule described in the unstructured free-text comment and the structured frequency shown by the system.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction for DACHL with ORBIS Medication version 04.00.01.00 in ORBIS version 84.44.04.00 or higher (release planned for second half of 2026 for DACHL)

Recommended actions to be taken by the customer:

- When editing prescriptions imported from external sources (e.g. Bundesmedikationsplan in Germany or ELGA Medication in Austria), be attentive to prescriptions with unstructured dosage and frequency information in free text. Review the comment at the top of the screen for guidance and manually change the frequency, if it does not match the intended schedule.
- Install the correction when available.

Please distribute this information to all those who need to be aware of it.

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	MST0110540 - Frequency of prescriptions defaults to "daily" if not specified in a structured way in the import source
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: