Urgent safety information

Required software update

Concerning

Nexus Medication 23.0.xx: Creation of a Federal Medication Plan via BMP Plug-In

28 Jun 2023

Sender:
NEXUS / DIS GmbH
Regulatory Affairs
Hanauer Landstr. 293
60314 Frankfurt am Main

Addressee:
Users, operators and distributors of Nexus Medication

Identification of the medical devices concerned:
Nexus Medication v23.0.10-23.0.18; BMP Plug-In

Description of the problem including the identified cause:
We would hereby like to inform you that a software error has been detected in the use of the Federal Medication Plan Plug-In in Medication (call via the discharge dialogue), which may occur from Medication 23.0.10 onwards.
Due to a software change, the line for the corresponding medication is completely omitted for prescriptions of preparations with expired central pharmaceutical numbers (PZN) in both current and already outdated versions of a federal medication plan. Correctly, the expired PZN should be indicated at this point.
This creates the risk that when a new BMP is created or a saved BMP is printed, the medication intended for the treatment is not listed, thus leading to an unconscious and unintentional discontinuation of the medication by the patient.
Since the dialogue for processing the discharge medication from which the BMP plug-in is called continues to clearly indicate expired PZNs, the risk of error for printing old BMPs is rated as higher than for creating a new BMP following the processing of a patient's discharge medication.

What measures are to be taken by the addressee?
The display of expired central pharmaceutical numbers in the BMP plug-in is not supported in the Medication version.
23.0.19 and upward corrected and reappears as expected:
If a PZN has expired, the note "PZN XXXXXXXX invalid:" appears in front of the drug name in the corresponding line in the BMP plug-in in the field "Trade name". If the BMP is printed anyway, the line only contains the expired PZN in the field "Trade name".
We recommend upgrading to Medication 23.0.19 (or higher) as soon as possible and, in the meantime, instructing users to carefully check federal medication plans for completeness.
It is also recommended to check the BMPs for completeness for patients who have been discharged since the installation of medication 23.0.xx.

Disclosure of the information described herein:
Please ensure that all users of the above products and other persons to be informed are made aware of this Urgent Safety Information. If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.

Please keep this information at least until the measure has been completed.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".

Contact person:
[redacted]
Regulatory Affairs Manager
[redacted]

[redacted]