



NEWSLETTER

JUNE 2023
ISSUE 2

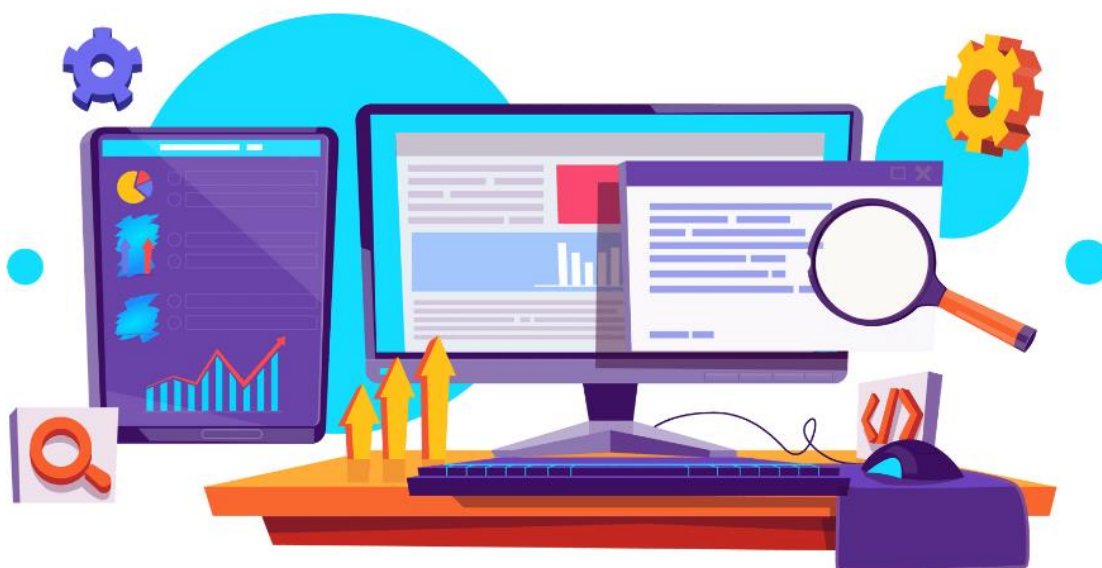
NMVS RELEASE – CORE 2.0 & Reporting Tool 2.0

For the latest NMVS Release – Core 2.0 & Reporting Tool 2.0, *Romania was the Pilot country.*

This was a key role in the functional and non-functional validation of the system's new version implementation.

The new versions: *NMVS Core 2.0 & Reporting Tool 2.0 were first implemented in our country, both in the test and the Production environment, where they were tested locally – 3rd – 18th of April.*

After finalizing the testing phase and approving the new system's versions, these were implemented one by one in the other countries.



Following the local testing, 7 minor defects were identified and reported, which the Arvato system developer will correct in the future releases.

The new versions were finally accepted because the defects found do not have a significant impact on the functioning of NMVS and the Reporting Tool, but rather improve certain functional flows according to the documentation and standard in the field.

NMVS Core 2.0 introduced system and workflow optimisations, like for example:

- ❖ Optimising the flow of inter-market transactions
- ❖ Optimisation and renewal of NMVS-EU-HUB security certificates
- ❖ Optimisation of error codes for V5 interface
- ❖ Introduction of new reports to facilitate new NMVS operational flows
- ❖ Fixing several bugs identified in previous NMVS 2.0 versions

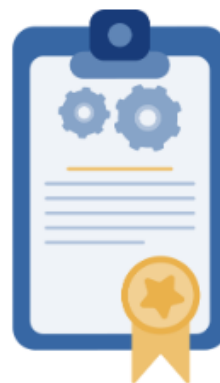


The technical optimisations mentioned above are not visible to End-Users, but their implementation is extremely important to improving NMVS' performance and security.

THE IMPORTANCE OF CORRECT CONFIGURATION OF INTERNAL APPLICATIONS TO THE NMVS

OSMR wishes to inform the NMVS's (National Medicines Verification System) End-Users that after analyzing the alerts generated by the NMVS, it has been revealed that *certain internal applications, connected to the NMVS, do not clearly highlight the alert generated upon scanning the medicine pack.*

Therefore, OSMR is reminding the End-Users of the responsibilities outlined by the Delegated Regulation (EU) 2016/161 and by the Order of the Ministry of Health no. 1.473 of November 22nd, 2018:



Pharmacies and Hospitals *verify the safety features* on the medicine packs when *decommissioning the medicines to the patient*, thus also *decommissioning the Unique Identifier* (DR, Art. 25).

The wholesalers *verify the authenticity of the Unique Identifier* (OMS 1.473, Art 17, paragraph 1). Moreover, they verify the medicine packs which they received from a wholesaler who is neither the manufacturer, nor the wholesaler holding the marketing authorization, nor the wholesalers who is designated by the marketing authorization holder (DR, Art. 20).

The configuration of the End-Users' internal applications, connected to the NMVS, *in such a way that they do not signal the alerts generated upon scanning*, allows the entry in the legal medicines' distribution chain of medicines that may not be authentic, *potentially harmful to the patient, the responsibility belonging exclusively to those End-Users, in accordance with the legislation specific to the pharmaceutical field.*



Thus, OSMR outlines the need to raise awareness on the importance of *the correct use of the NMVS, of compliance with legal obligations and implicitly the importance of ensuring patient safety.*

