FAQ – what to do if …

…the NSOL system is not available = medicinal products subject to anti-counterfeiting legislation must continue to be verified upon dispensation, i.e. the authorized dispenser must scan the 2D code of each package and enter the unique identifier into the pharmacy/distribution software. As soon as NSOL is available again, all of the 2D codes scanned when it was unavailable will be submitted by the pharmacy software for subsequent verification.

…I don't know whether NSOL is available or there is an error in the connection or availability of the internet connection of the end user SW = on the NOOL website: www.czmvo.cz, under the NSOL status tab (https://www.czmvo.cz/cs/stav-nsol/), you will see a system status light; green means that the system is available without restriction.

…the pharmacist scans incorrectly (switched Y/Z or lower case/CAP letters), an alert is triggered, the pharmacist notices and switches the keyboard or turns off "Caps Lock". Can he scan again and not wait for the MAH alert to be resolved? = Yes, as soon as the pharmacist eliminates the errors and successfully re-verifies the medicinal product subject to anti-counterfeiting legislation, he can dispense the package to the patient. Even in the event that the medicinal product has already been verified once, originally triggering an alert due to a mistake on the part of the end user (pharmacist). The second successful verification eliminates the error on the part of the end user. The alert will then be closed by NOOL.

…the pharmacist dispenses a package of medicine, the customer fails to pick it up, the re-activation deadline is missed (10 days at the same place) – the distributor refuses to take the medicinal product back = It is recommended to carry out verification at the moment of dispensation to the customer, not in advance. The distributor is not obliged to take back packages that can no longer be verified in NSOL for this reason.

…it is not possible to verify a medicinal product, but the NSOL system is working = check the internet connection on your end and/or contact your IT SW provider or IT support.

…the pharmacist scans the 2D code of a medicinal product subject to anti-counterfeiting legislation and an alert is triggered = the medicinal product with alert information should be quarantined – marked with a unique alert code (alert ID), or the alert ID should be saved in the end user's SW along with records of the package, which can then be used to return the package to the distributor. Wait for the alert to be resolved for a period of 14 days (if this does not concern an error on the part of the end user – i.e. the reader is set up properly and there was no error involving switched Y/Z or lower case/CAP letters). The proper setting of the reader can be checked with a test scan. The alert will be resolved in the NOOL system within 14 days, and its status can be viewed there. If the medicinal product cannot be dispensed, then it will be returned to the distributor after 14 days.

…the resolution status of alerts for medicinal products quarantined at our pharmacy is unknown = once an alert has been generated, the IT SW of the pharmacy can check the status by querying the alert management system operated by NOOL via API. If the IT SW of the end user does not offer this functionality, it is possible to contact your provider of pharmacy/distribution IT SW to determine the alert resolution status.

…the 2D code is illegible = verify using the human readable data elements (product code (PC), serial number (SN), batch number (LOT) and expiration date (EXP)). All 4 of these must be entered into the system. If the data elements still cannot be read through the human readable data elements, this is a regular return. The medicinal product can then be returned using the standard procedure.

… the package only lists the month and year and I need to enter the expiration date through manual verification = as of November 2020 under R 7.0 NSOL the day of expiration is not considered when triggering alerts; only the month and year).

... the patient wants to return a medicinal product that has already been dispensed = according to CR legislation this is not possible. According to the regulation, a medicinal product can only be returned to "Active" status if it has not already been dispensed.

…I have a package with no security elements. How should I proceed? = you should check whether it was released by the manufacturer before 9.2.2019 and whether it falls under FMD (medicinal products subject to medical prescription, unless included in the list set out in Annex I to Commission Delegated Regulation (EU) 2016/161, or not subject to medical prescription included in the list set out in Annex II to this Regulation).

…I need to contact the NOOL call center =
by e-mail: Operational support: support@czmvo-alert.cz
Registration support: registrace@czmvo.cz
General information: info@czmvo.cz
by telephone (1st or 2nd options at) +420 224 834 153, +420 224 834 154, +420 224 834 155

…this is a foreign medicinal product delivered through individual import = foreign medicinal products subject to anti-counterfeiting legislation provided with security elements must be verified in the same way as those intended for the Czech market. An "intermarket operation" must be used to verify the medicinal product in the database of another state for whose market the medicinal product was originally intended.

…I want to transfer the medicinal product to another warehouse/storage location (from the perspective of FMD) = do not decommission the unique identifier (UI) (never use "Supplied" – this manner of decommissioning the UI should only be used when dispensing the package to the patent or to a health facility department). This is not a standard procedure that can be used (according to the amendment to the Pharmaceuticals Act this approach cannot be used between a pharmacy and distributor, even if they have the same IČO; the transfer between storage at different locations of the same distributor should mean physical transfer, but the UI should not be decommissioned - do not use the status "Discharged" or "Supplied").

…is there a prescribed order of information in simple text? = the order of data elements is not determined, although it is recommended that PC go first.

…a medicinal product repeatedly cannot be verified (alert is triggered), then it is successfully verified. Can I dispense this medicinal product? = if you discover and fix the error on your part as the end user, see above (e.g. you switch off Caps Lock or switch over to the proper keyboard). After successful verification of the scanned 2D code the package can be dispensed to the patient.

… Do I want to return the medicinal product to the distributor (from an FMD perspective)? = from the pharmacy system (or another manner depending on the process used at your pharmacy) determine which packages should be returned (i.e. a medicinal product has been in quarantine for at least 14 days and the alert has not yet been resolved by MAH, and this does not concern an error on your part as the end user). Then create a return to the distributor that supplied the medicinal products to the pharmacy. Upon receipt the distributor will verify whether the goods trigger an alert, if so, they will be placed in quarantine and resolved by MAH.

…following successful verification when dispensing to the patient, I find the product's ATD has been compromised = the medicinal product with compromised ATD should not be dispensed to the patient. Prepare to return it to the distributor and use the system to report the incident to SÚKL. Nonetheless, if the situation requires, (e.g. during patient education), as a pharmacist you may break the ATD in front of the patient and then dispense the package.

…a medicinal product is permitted by the Ministry of Health in accordance with Section 11 let. r) of the Pharmaceuticals Act, but an alert was triggered. After obtaining this information is it possible to dispense this package even without successful verification? = the IT SW of the end users should record this information based on data provided by SÚKL, and is thus permitted to dispense this medicinal product despite the alert. Currently, the NOOL alert management system closes the alert case based on the paragraph mentioned above, i.e. via API it is also possible at the pharmacy to see the change in alert status and then dispense the medicinal product (in case the information is not available in the pharmacy IT SW).

… it is a medicinal product that is not dispensed as a whole, but only partially in a so-called multipack. The verification and decommission is only done once, the first time the pack is opened and the content used (even if only a part of it) regardless of whether it is a blister, solution sachet, etc.

…it is a suspected counterfeit = if after investigating the alert MAH determines the product is a "Suspected counterfeit", NOOL is obliged to complete the audit by not only determining where the alert was generated, but also the end user, specific facility and person who triggered the alert. It will then notify SÚKL, the European Commission and the European Medicines Agency about the suspected counterfeiting. Subsequently, a standard investigation of counterfeiting will take place.