Recommendations for wholesalers whose medicines are contractually verified by a third party

In order to comply with the **Commission Delegated Regulation (EU) 2016/161**, the Czech Medicines Verification Organisation (CZMVO) offers two options to wholesalers who have contractually delegated their obligation related to medicine verification as per the „Falsified Medicines Directive (FMD)" to a third party.

Option A: EVA portal

The first option is a solution via the so-called EVA portal (Emergency Verification Application). The EVA portal serves primarily as an emergency verification system used to verify the authenticity of medicines in case of a problem with the end user's FMD application or device. Using this solution offers limited authentication possibilities. In the portal, you can only verify and decommission medicine, by entering data manually, without using a reader. You can log in to the EVA portal using the same access data used to log in to the CZMVS. If you choose this option, there is no need to use pharmacy software. In such cases, the use of the EVA portal is also approved by the National Certificate Authority (SÚKL).

You can log in to the EVA portal here (https://eva-cz.nmvo.eu).

Registration process:

STEP 1: Registration and signing of the Agreement (choosing the "EVA (Solidsoft Reply)" software and providing information on who verifies medicines on behalf of the company)

STEP 2: Connect to CZMVS

STEP 3: Create a location in CZMVS – one location is sufficient (even if more locations exist)

STEP 4: Creation of the device - generate and store the location ID and secret key (do not connect it to the pharmacy software)

STEP 5: Log in to the EVA portal (important to meet FMD and SÚKL requirements)

STEP 6: If necessary, log into the EVA portal, manually upload medicine data and verify - limited options (verification, decommissioning) - see instructions)

Option B:

The second option, which enables medicine verification, is to connect to the CZMVS via pharmacy or distribution software in a standard way. In such cases, it is necessary to connect a verification device to a location created in the CZMVS via this software.

Both options require *Agreement on the use of the NSOL(=CZMVS) by end users* to be signed and to be connected to the CZMVS.

The CZMVS registration procedure and methods and possibilities of its use can be found in the documents on the czmvo.cz website in the System Users/Pharmacists and System Users/Distributors sections.

If necessary, do not hesitate to contact CZMVO via email registration@czmvo.cz.

Q&A:

Do both options meet FMD requirements?

Yes, they do.

Do both options meet the requirements of SÚKL?

Yes, they do.

In the case of "Option A", if I create a location under my login, could that cause a problem in the system for the original location (created under the company that verifies the medicines for us)?

No, it couldn't. You only create the location, you do not connect it to the verification device through the pharmacy software.

Do I have to log in to the EVA portal even though I am not currently planning to verify the medicines?

Yes, it is important to log into the EVA portal as part of the registration process in order to confirm that the company is able to log into the portal and verify medicines if necessary.

Which option would you recommend to us?

Both options are possible, "Option A" does not involve any additional costs for the pharmacy software, "Option B" offers full use of the CZMVS and the possibility of medicine verification.

Under which location ID will the medicines be verified?

Medicines will be verified under the location ID created under the company that contractually verifies the medicines.