

Planned changes in the SUKL communication environment

Distributors of medicinal products for human use

Updated on August 17, 2017

Due to new technologies implementation, the communication between the distributors of medicinal products and SUKL will be significantly affected by the modifications of the operated systems and interfaces.

Currently, the distributor reports on deliveries of distributed medicinal products for human use into the SUKL information system via electronic mail.

The reporting on deliveries of distributed medicinal products for human use pursuant to Section 77 (1) f) of Act No. 378/2007 Coll., on Drugs will be changed according to the guideline DIS-13, version 5, adopted on May 1st 2017 and effective as of September 1st 2017, available [here](#).

The reporting of deliveries of distributed medicinal products for human use for September 2017 shall be submitted to the SUKL reporting system via data interface, created for this purpose or by filling in the web form (the reporting form will be published the latest on September 1st, 2017 at <https://pristupy.sukl.cz>).

SUKL prepared a new system the External identities (further referred to as „EI“), providing registration of entities (legal entities and natural persons) authorised to communicate with SUKL. The system was launched on May 6, 2017 and enables the authorised entities to generate and download the certificate for communication with SUKL.

- The distributor shall generate and download the certificate at <https://pristupy.sukl.cz>. This certificate may be used for reporting either within the particular system used by the distributor or via the web form.
- To access the system EI use access data that have been sent to you in a letter by SUKL. In case this information is not available and the reporting was submitted to the system DIS – 13 by using own system, the administrator of the particular system may be requested to provide the required data (the data is available in the distributor's system). For detailed information see the manual available at <https://pristupy.sukl.cz>.
- [The system for reporting of quality defects](#) (launched in June 2017) can be accessed only by using the communication certificate EI (similar as in DIS13).

The system for reporting quality defects, launched in June 2017 will be updated by SUKL staff based upon newly submitted reports. The distributor possessing the issued and correctly implemented new communication certificate, is authorised to access the system for reporting quality defects. The use of this system is determined by the implementation of the interface of the system for reporting quality defects into the internal system of the distributor (this has to be carried out by the supplier of the particular information system).