Národní organizace pro ověřování pravosti léčiv

Medicines verification of the authenticity begins in pharmacies

In Prague, 7 February 2019. In accordance with Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use, as of 9 February 2019 medicines must be verified before being dispensed to patients. In the Czech Republic the National Medicines Verification Organization (NOOL, CZMVO) is responsible for implementing and operating the system for verifying the authenticity of medicines. More detailed information is available at www.czmvo.cz

Readiness of the national system for verifying the authenticity of medicines

Czech medicines verification system (NSOL, CZMVS) is technically ready and functional. NOOL has published a dossier for the procedure, which will be regularly updated based on ongoing experience.
As of today, 1,338 pharmacies and distributors (end users) are connected to the system, while the unique codes of 21,209,260 medicinal products of 186 marketing authorization holders (manufacturers) have been entered into the system.

Protective features include the unique 2D code and anti-tampering device to prevent handling of package contents (e.g. stickers). These protective elements are placed on the packaging by the manufacturer (marketing authorization holder), which before market release will enter the data of unique identifiers into the system (through a European "hub" to the national repository). The authenticity of each original box can then be verified during its entire journey from the manufacturer to final dispensation to the patient.
This measure was implemented due to the increasing danger of falsified or stolen medicines entering the European distribution system.

Availability of medicines top priority

According to the Chairman of the Board of Directors of NOOL, Jakub Dvořáček, MHA, the current likelihood of falsified medicines appearing in the official Czech distribution network is negligible. If for any reason pharmacists are unable to verify the unique code, then they will proceed at their own discretion. According to the amendment of Act **No. 378/2007 Coll., on pharmaceuticals,** that was approved by the Chamber of Deputies of the Czech Parliament and then by the Senate, sanctions for possible errors in the verification procedure will be postponed until 1st January 2020 (for more details see Senate press release 30).

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The availability of medicines was also emphasized by Czech Minister of Health Adam Vojtěch, as a priority. He said: "Until the end of this year neither the Ministry of Health nor the State Institute for Drug Control will sanction pharmacists for dispensing medicines to patients even if they are not able to verify and check the identifier of the medicinal product in the data repository, if in good faith they are reasonably sure such medicinal product is authentic. This good faith may stem from experience to date, as well as the system of risk management that has been implemented, including measures such as accepting medicinal products only from established and proven distributors of medicinal products, visual inspection of packaging integrity, etc."

According to the amendment, in certain cases the Minister of Health may also approve the dispensation of an entire batch of medicines that could not be verified for technical reasons, provided there is a threat to the availability of irreplaceable medicinal products, and thus also to patient health. A positive role in verifying the authenticity of medicines is also played by distributors (AVEL association), who have agreed to verify each batch of medicines before taking possession of them from manufacturers for further distribution. This will minimize instances of unsuccessful verification due to technical errors when entering unique code data into the system.
A pilot program in the CR has already confirmed the full functionality of the Czech national system for verifying medicines.

Mgr. Jakub Dvořáček, MHA, representing NOOL

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NOOL, the Czech National Medicines Verification Organization, is a non-profit organization founded for the purpose of managing the Czech national system for verifying the authenticity of medicines (NSOL). It is responsible for the proper functioning of the system and reporting of unsuccessful verification of medicinal products, especially when counterfeits are suspected.

The members of NOOL are:
The Association of European Distributors of Pharmaceuticals, AEDL
The Association of Innovative Pharmaceutical Industry, AIFP
The Czech Association of Pharmaceutical Companies, ČAFF
The Association of Wholesale Distributors of Pharmaceuticals, AVEL
The Czech Chamber of Pharmacists, ČLnK