LiMVO
liechtenstein medicines
verification organisation

Zug, 18.02.2019

Ladies and Gentlemen,

We are very pleased to inform you that the National Medicines Verification System for Switzerland and Liechtenstein (NMVS-System) is finally connected to the European Hub and is productive. Cooperation partners of the SMVS GmbH, can now upload the serial numbers and master data of their concerned products to the EU hub with a market authorisation for Switzerland and Liechtenstein. The target market for the uploading is "CH" for both Switzerland and Liechtenstein.

Please consider following 5 points in respect with the implementation for Switzerland and Liechtenstein;

1. Cooperation SMVO, LiMVO and EMVO

EMVO confirms that the LiMVO, as the national verification organisation for Liechtenstein, is entitled to be connected to the European hub with its NMVS system. This allows Liechtenstein end users to immediately start the on-boarding process to the National Medicines Verification System (NMVS-System). With the NMVS-System, products with a target market in the EEA or Switzerland can be verified and decommissioned without restrictions.

Thanks to the customs union - and the very close cooperation between the stakeholder groups of Liechtenstein and Switzerland - the LiMVO grants Swiss end users access to the NMVS-System. This is done via the standard "supranational" functionality of Solidsoft Reply's NMVS Blueprint system. It means, that swiss end users can verify and decommission concerned products with a swiss marketing authorisation without restriction.

2. supply of products from the EEA region to Switzerland (DR (EU) 2016/161, Art. 22 a))

EEA products with target market outside the custom union between Switzerland and Liechtenstein, exceptionally entering the Swiss market (e.g. shortages), must be marked as “Export” (wholesaler) or “decommissioned” (other end user) by the entity in the EEA despatching them. Such product can then only be verified by Swiss and Liechtenstein End User, as they have already been decommissioned in the EEA.

Important: A decommissioning attempt of an EEA product imported into Switzerland by an end user triggers an "alert", as the product has already been decommissioned in the EEA region. Alerts due to such products may be ignored for the moment. We are working on a technical solution.

3. access by the Swiss authorities to the NMVS-System

LiMVO will grant the Swiss authorities (NCAs) access to the NMVS-System but will restrict data access to Swiss transactions only. Reports on cross-market transactions involving data from the EEA will not be accessible to the Swiss authorities.

4. implementation of the DR (EU) 2016/161 in Liechtenstein

Once the DR (EU) 2016/161 has been incorporated into the EEA Agreement, the following will happen in Liechtenstein:

- For products covered by the custom union agreement with Switzerland, nothing changes -> 98% of the products.
- Products imported directly from an EEA country must be decommissioned in Liechtenstein in accordance with the Delegate Regulation (EU) 2016/161. Concerns about 2% of the products sold.

The process of adopting the Delegated Regulation (EU) 2016/161 has not yet been completed, so that as of 9 February 2019 there is no legal obligation for the dispensing persons in Liechtenstein. Further information will follow in due time.

5. implementation of Art. 17a of the Therapeutic Products Act in Switzerland

After 9 February 2019, the following will happen in Switzerland:

- In principle, nothing will change except that 75 pharmaceutical companies are already voluntarily implementing the application of the two security features (serial number and anti-tampering device) on the packages for prescription medicines. This represents approximately 64,000,000 packs sold per year.
- In the course of 2020, Art. 17a HMG, together with the Ordinance, will enter into force. After the law comes into force, the National Medicines Verification System must be established in accordance with Art. 17a HMG, para. 3 and financed by the pharmaceutical industry.

EMVO, SMVO and LiMVO jointly welcome the fact that a solution has been found which is supported by all stakeholders involved. It will enable Liechtenstein to fulfil its future obligations under the Delegated Regulation once it has been incorporated into the EEA Agreement. At the same time, it allows Swiss stakeholders interested in maintaining the high level of supply chain security and patient safety in Switzerland to use the NMVS-System on a voluntary basis.

If you have any questions or suggestions, please do not hesitate to contact us.

With kind regards

LiMVO Stiftung für die Verifizierung von Arzneimitteln in Liechtenstein

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