18 June 2018

Dear Vnr Service user,

MEDICINES VERIFICATION NOTIFICATIONS

BACKGROUND AND AIMS

Implementation of the Finnish medicines verification system is approaching. The system is based on the requirements of the Falsified Medicines Directive as well as the specifying Delegated Regulation. Safety features, that is, unique package identifier and tamper evidence must be added to prescription medicine packages. Unique identifiers need be uploaded to the European central repository, that interacts with the Finnish medicines verification system. The national Finnish system is utilized by wholesalers, pharmacies and hospital pharmacies.

The system must be functional by 9th of February 2019 at the latest. Thence new prescription medicine and OTC omeprazole packages that are released to market must contain the unique identifier and the tamper evidence. Packages released before that may not necessarily contain the unique identifier.

The system will be implemented in phases in Finland, starting from **the 18th of June 2018**. This way the reliability and smoothness of the system will be ensured.

Actors in the pharmaceutical supply chain, particularly pharmacies, need up-to-date and clear information on which packages must be verified and decommissioned from the repository system when the medicine is dispensed.

For this purpose, a new medicines verification notification is introduced in the Vnr Service. Pharmaceutical companies will make this notification like other notifications. Pharmaceutical Information Centre delivers the information of the notifications to wholesalers and pharmacy/hospital pharmacy system suppliers to ensure efficient and reliable action. Information channels already in use will be utilized to ensure the most efficient use of the resources of different actors.

MAKING A MEDICINES VERIFICATION NOTIFICATION

The pharmaceutical company makes the medicines verification notification for the **first** batch of packages containing the safety features. If the batch has already been released, the notification will be made retrospectively.

The notifications are made in the Vnr Service. The service utilizes the basic information of medicines already present. The medicines verification notification functions similarly to other notifications, e.g. the product code notification.

Medicines verification notifications can be made from **the 18th of June 2018** onward.

Pharmaceutical Information Centre delivers the notifications and the necessary information to wholesalers as well as pharmacy and hospital pharmacy system providers. The notifications are delivered to the former right after **the 18th of June 2018** and later also to the National Pharmaceuticals Database (ePrescription) according to the development schedule of the latter in 2020.

The information is delivered once a day cumulatively. In this way either all and/or a part of the notifications e.g. the newest ones can be utilized according to varying needs in e.g. pharmacy systems.

The medicines verification notifications only pertain to Finland, not other Nordic countries.

HOW TO MAKE A NOTIFICATION

Check before making the notification that

- the package in question has
  - 2D data matrix containing the product code (GTIN/unique NTIN), unique serial number, batch and expiry date
  - tamper evidence
- the packages of the batch in question have been uploaded to the EU hub
- product code (GTIN/ unique NTIN) has been saved for the Vnr number in the Vnr Service

Making a medicines verification notification in the Vnr Service

- Go to the Medicines verification notification form
  - https://vnr.fi > Notification forms > Medicines verification
- Search for the package in question by Vnr or trade name
  - The Vnr Service will check that you may make a notification
    - for a product covered by the Falsified Medicines Directive
    - only once for each package
- Choose the product code of the package for the notification
  - Dropdown menu presents all the product codes saved for the Vnr, choose the right one from the list
  - If the product code in question (GTIN/unique NTIN) has not been saved for the Vnr, make the product code notification now by the direct link in the medicines verification notification
- Fill in the batch number and expiry date (mandatory information)
  - Expiry date is given in format: dd.mm.yyyy
    - Exp or Kestoaika 10-2020 -> 31.10.2020
    - Käyt. viim. 10-2020 -> 31.10.2020
    - Käyt. ennen 10-2020 -> 31.09.2020
  - IT systems utilize also batch and expiry dates as data presentation criteria, because effective dates might be estimates
- Fill in the **estimated** effective date of the notification
  - **Estimated** = date when the batch in question is available for the supply chain
  - If no effective date is filled in, the date will automatically be the date of making the notification
  - The effective date can be filled in as e.g. the batch release date
- Medicines verification notification has been saved in the Vnr Service, when after clicking the send button you have got the **confirmation**: Thank you! Notification data has been stored in the Vnr number information.
- If you need to modify the notification later, please contact Pharmaceutical Information Centre at vnr@vnr.fi.

Retrospective information on packages already released

- A medicines verification notification must be made retrospectively also for already released packages containing safety features
- If a batch is already on the market, the date of making the notification can be filled in as the effective date

REPORTING

Pharmaceutical companies may take reports on the medicines verification notifications they have made e.g. for documentation. Reports can be taken 24/7.

https://vnr.fi > Reports > Medicines verification

Pharmaceutical Information Centre keeps track particularly of significant changes in shelf life and notifies actors specifically on shortened shelf life in combination with medicines verification notifications. Pharmaceutical Information Centre reports regularly the status of the medicines verification notifications to The Finnish Medicines Verification Organisation FiMVO.

The medicines verification notifications are being implemented according to the specific wishes and needs of stakeholders for a **transition period**. This is to ascertain the reliability and smoothness of the system. This is not a requirement by the authorities. When a medicines verification notification has been made for all packages included in the Falsification Medicines Directive, this notification type is removed from use.

ADDITIONAL INFORMATION

More information on the medicines verification system can be found at www.laakevarmennus.fi.

Pharmaceutical Information Centre Ltd answers any questions concerning the medicines verification notifications with pleasure. Questions concerning the notifications may be sent by email to vnr@vnr.fi.

The Finnish Medicines Verification Organisation answers any questions concerning the medicines verification system with pleasure. Questions concerning the system may be sent by email to info@laakevarmennus.fi.

With best wishes from
Pharmaceutical Information Centre

vnr@vnr.fi
www.laaketietokeskus.fi