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Subject: Implementation Falsified Medicines Directive (FMD) in the Netherlands

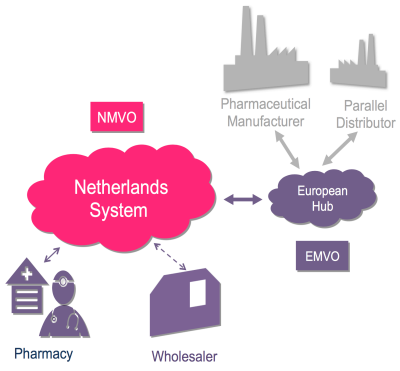
Dear Madam / Sir

We send you this letter because your organization has one or more Marketing Authorisation holdership(s) for Prescription Medicines in the Netherlands. On the 9th of February 2019, the delegated regulation from the European Commission will be active, the Falsified Medicines Regulation (FMD). The Goal of this Regulation is to eliminate falsified medicines within the regular distribution channels. In this letter, we will inform you about the impact of de delegated regulation on your organization and how the implementation is organised within the Netherlands.

Background

Short description of the FMD

From February 2019 onwards every pack of prescription medicine must have a unique 2D-Data Matrixcode on the pack. Manufactures and parallel distributors are responsible for applying the 2D data matrix on the pack and also a sealing mechanism so it is clear pack is not tampered with. The unique code is uploaded by Manufacturer of Parallel distributor to the European system. Pharmacies will scan the pack before handing it over to a patient. The scanned 2D-data matrix information is checked in the national system to ensure that the pack still has the status that it can be dispensed. If the system gives the feedback that the pack may not be dispensed the Pharmacist will not dispense the pack to the patient



Implementation in the Netherlands

In the Netherlands the implementation is facilitated by the non-profit foundation NMVO (Stichting Nederlandse Medicijnen Verificatie Organisatie). The NMVO is an initiative from representatives from manufacturers of pharmaceuticals, parallel distributors, wholesalers and pharmacists (BG Pharma & VES, Bogin, KNMP en Vereniging Innovatieve Geneesmiddelen).

The NMVO will build, test and maintain the national system in the Netherlands. The NMVO will also inform all concerned parties about the progress and will offer operational support to Pharmacists and Wholesalers to connect to the national system

Impact on your organisation

The implementation of the directive has impact on your organisation in the following areas:

- From February 2019 onwards prescription medicines will only be dispensed to patients if the pack contains:
  - A 2D Data matrix that contains a unique code
  - A sealing mechanism to ensure that the pack has not been tempered with
- Connection to the European System to upload the unique numbers of the packs that will be distributed to the European markets.
- Financial contribution for the build, testing and maintenance of the National IT system.

In the directive it is stated that Manufacturers (including parallel distributors) (Marketing Authorisation Holders) will bear the costs related to the realization and maintenance of the national system. The adoptions that are needed in the IT systems of pharmacists, hospitals and wholesalers are not part of these costs. Pharmacies, hospitals and wholesalers will have to bear the costs related to the adaptation of their systems. On European level it was decided that the basis for the distribution of the costs will be a form of flat fee per Marketing Authorisation Holder.

Financial impact in the Netherlands for 2017 and 2018

The implementation of the national system is a complex process due to the amount of affected parties and the fact that the system has to work immaculately on the 9th of February 2019 the NMVO has taken the initiative to start swiftly with the realization of the national system. A supplier has been selected to realize the IT system. Contracting this supplier will only take place if the financial obligations towards the supplier are covered.

NMVO Stichting Nederlandse Medicijnen Verificatie Organisatie

The NMVO has setup a budget for the start-up phase 2017 and 2018. The cost estimation during this period is 2,7 Million Euro. The NMVO has setup the following guidelines to cover these:

- The implementation must be as cost efficient as possible
- Timely financial commitment from a Marketing Authorisation Holder must be rewarded. Timely commitment enables the NMVO to start quickly with the realisation and thus enabling a controlled and cost efficient implementation

The exact number of Dutch Marketing Authorisation Holders that will utilize the system is not clear at this moment. The board of the NMVO assumes that 120 to 160 Marketing Authorisation Holders will utilise the system by the 9th February. 2019. Based on these numbers the NMVO has decided that the one-off entrance fee for now will be € 25,000. - ex VAT per Marketing Authorisation Holder. All Marketing Authorisation Holders that will connect to the system will have to pay the one-off entrance fee, this is not coupled to the moment of connecting to the system.

To stimulate early commitments the board of the NMVO has decided that the amount that remains after all costs of the start-up phase have been covered will be distributed over the Marketing Authorisation Holders that have shown their commitment by paying the entrance fee before 1st of March 2017. The pay back will be performed in 2019.

Financial impact in the Netherlands in 2019 and onwards

From 2019 the yearly costs for maintaining the national system will be distributed over the Marketing Authorisation Holders that are utilizing the system. The distribution will be done based on a to be established form of flat fee per Marketing Authorisation Holder.

Our question to you

Can you provide us, prior to the 15th of February 2017, for which Marketing Authorisation Holdership(s) we can send your organisation an invoice for the entrance fee?

If this letter raises any questions, please feel free to contact the NMVO by sending an e-mail to info@NMVO.nl

With kind regards on behalf of the Board of the NMVO,

NMVO Stichting Nederlandse Medicijnen Verificatie Organisatie

M.L.A. (Martin) Favié, Treasurer