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DG Inspection/Authorisations Division

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Circular No. 654
To the attention of the inspectors involved in controlling the chain of distribution of medicinal products

Your letter from	Your reference	Our reference	Annex	Date
		EP-00013565		07/02/2024

Handling of FMD alerts by users in the context of verification of medicine packaging using the Belgian Medicines Verification System (BeMVS) and the Alert Management System (NMVS Alerts)

Circular 647 already stipulated the application of the medicines verification system developed under Delegated Regulation 2016/161/EU.

Recently, the system was found to have once again proven its usefulness in intercepting counterfeit versions of medicines based on semaglutide. These counterfeit medicines posed a direct and clear threat to public health. The FAMHP therefore stresses the importance of the correct and effective use of the system by all actors involved in the medicines distribution system, including the necessary quarantine procedures if the system generates an alert when verifying or decommissioning medicines.

In practical terms, the actors involved in an alert should therefore keep the product in quarantine until a clear explanation is found for the alert, and until it can be confirmed that the product was properly decommissioned.

At this stage, all actors involved are connected to the system. In addition, the so-called "alert rate" appears to be lower than 0.05 % of the number of verified medicines. Furthermore, a system is provided by the EMVO and BeMVO to handle these in a systematic and efficient way in the event of an alert. So we expect appropriate procedures, including quarantine, to be systematically followed in the event of an alert.

The FAMHP therefore calls for due attention in inspections to ensure that:

- the quarantine rules, especially at the level of pharmacies open to the public, hospital pharmacies and distribution authorisation holders, are properly met in the event of an alert. A number of rules were therefore developed in consultation between the BeMVO and the FAMHP and communicated to users through the BeMVO's website. These should be followed when handling and, if needed, preventing alerts from escalating. These rules were also communicated internally;
- working with the BeMVO system is correctly documented in the quality systems of the actors involved;
- all actors involved use the system effectively and continuously. In case of technical problems, the actors involved take the necessary measures to solve these problems as soon as possible;
- in the event of any problems with uploading data to the database, the responsible for placing medicines on the market takes the necessary steps to add missing data as soon as possible or to rectify incorrect data as soon as possible;
- enforcement action is taken through formal warnings where necessary, and, if necessary, proposals for reaching an amicable agreement are made, or an official report is drawn up in cases

where, after being notified, the actors involved do not take the necessary steps to follow these rules or do not draw up and implement adequate corrective action plans.

In practical terms, I therefore ask you to actively check the above points during your inspections.

Yours faithfully,

Digitally signed by Hugues Malonne (Signature)
Date: 2024.02.09 14:33:56 +01'00'

Hugues Malonne
Chief Executive Officer