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federal agency for medicines and health products

Directorate-General Inspection – Authorisations Division

Circular no. 647
To the attention of the Directorate-General for Inspection of the FAMHP

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Further practical guidelines for the start-up phase of the Falsified Medicines Directive

Dear sir,
dear madam

Circular 644 provided a number of practical guidelines to handle possible problems during the start-up phase of the Falsified Medicines Directive[i]. The circular determined that these guidelines should apply to the end of April 2019. The FAMHP followed the situation closely and has decided to extend this period. The guidelines in circular 644 will now apply until September 1, 2019.

On September 1, 2019, the drug control system must be fully operational and used consistently. This means, among other things, that if the system detects a possible falsified medicine, the affected stakeholder will hold the medicine in quarantine until they have received a decision on whether or not the packaging has been approved or not.

Below you will find the actions to be taken and the timing by stakeholder:

Marketing authorization holders (MA) who are not yet connected to the drug control system (Belgian Medicines Verification Organisation - BeMVO)

What?	When?
Registration with the BeMVO	Before the release of the first lot with serial packaging
Connection to the EU hub to upload data (if the MA has serial products ready for distribution at that time)[ii]	01 August 2019
Solving quality problems in the uploaded data[iii]	01 September 2019

Wholesalers(-distributors) and end users[iv]

What?	When?
Registration with the BeMVO (https://bemvo.be/)	15 July 2019
Connection to the BeMVO system[v]	15 August 2019
Operational verification and decommissioning	01 September 2019
Effective use of alarm procedure[vi]	

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Only wholesalers who physically handle FMD products must connect to the BeMVO system. A wholesaler who is the MA holder, can also work via their connection as an MA holder. Wholesalers are required to verify return shipments from pharmacies. The FAMHP will allow wholesalers to offer for sale return shipments that show an error message during verification until September 1, 2019, on the condition that there is no suspicion of counterfeit. The packaging must be undamaged, the anti-tampering device (ATT) must be intact, the dug was returned by the purchaser of it... They may only do this if they follow the GDP guidelines.

Additional note

A wholesaler(-distributor) may also deliver in the place of a pharmacy:

- to the military;
- to vaccinators and vaccination centres in the light of preventive medicine;
- to shipping companies.

In that case, the wholesaler must make sure that the drug is decommissioned.

Conclusion

The FAMHP and BeMVO will continue to closely monitor the situation. The FAMHP emphasizes that it is important to fully use the new protection of the Falsified Medicines Directive as quickly as possible. **Every user** must therefore accept their responsibility and **ensure that their system is operational**, possibly through the intervention of their external software/solution/hardware provider. Users who **do not meet the standards**, are not working according to the law and risk **sanctions**. The availability of drugs for the patient and the protection from falsified medicines remain crucial points for the FAMHP.

With courteous regards

Xavier De Cuyper,
Chief Executive Officer of the FAMHP

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[i] Directive 2011/62/EU; Falsified Medicines Directive (FMD)

[ii] MA holders that had already built up an inventory and will not release products before August 1, 2019 are strongly advised to register and to apply the technical aspects to avoid problems with uploading and blocking after September 1, 2019.

[iii] For example, guaranteeing legibility, quality and conformity of the data matrix, correcting erroneous uploaded data, providing GTIN codes to APB/FAMHP, uploading missing data for serial packages (even if released before February 9, 2019), making sure that the expiration date in the data matrix and that in NMVS correspond perfectly (00/01/20) in the data matrix is also 00/01/20 in the hub and not 31/12/29), systematically checking that (partial) lots are actually uploaded, verifications of sample packaging, notifying BeMVO of so-called Indian packs on the market.

[iv] End users are public and hospital pharmacists, preparation license holders and IMP license holders that physically receive FMD products (verification/deactivation for IMP may occur via the connection of the MA holder)

[v] Including accepting the "terms & conditions" as quickly as possible, using the correct FMD software module, use correctly configured scanner (e.g. qwerty vs. azerty keyboards, capital letters vs. small letters, see the BeMVO website for a test page), correct and exact sending of the data read.

[vi] https://bemvo.be/wp-content/uploads/2018/10/FMD-Falsification-alerts-20181001.pdf