Subject: Business Go Live in France - Connection to the European Hub in production

Madam, Sir,

After several months of development, testing, and validation, France MVO is pleased to announce that the connection date for France MVS to the European hub has been set for

September 5, 2018

From this date, laboratories with authorized access to the European Hub will be able to send data from serialized packs destined for the French market to the French database – by loading them in the European Hub.

In order to best prepare this crucial step of the implementation of Directive 2011/62/EU in the fight against falsified medicinal products, France MVO would like to remind you of the key points of this connection:

- In line with EMVO recommendations, you must retrospectively load data for all serialized medicinal products released prior to September 5, 2018 - to minimize alerts in the system.

- According to the requirements of the French Authorities, it will not be possible to send product codes other than CIP 14 (NTIN). Any pack placed on the French market with a code other than CIP 14 may cause significant issues in the information systems of dispensers and distributors preventing reimbursement. Any non-CIP 14 code will be rejected in the short term by the French system.

A working group has been established with the objective to define the process for administering the multi market packs using the GTIN code without disrupting national reimbursement procedures. France MVO will communicate the conclusions of this group as soon as they are validated by the French authorities, as well as the procedures for managing multi-country packs in the NMVS.
In the event that this letter raises other questions, do not hesitate to contact us at info@france-mvo.fr. All useful information is available on the websites of France MVO: www.france-mvo.fr and EMVO: https://emvo-medicines.eu/.

We hope that you have given this letter your full attention, and I wish you all the best.

Patrick Oscar
Delegate General
France MVO