

Impact of Falsified Medicines Directive (2011/62/EU) on look and feel of Amgen packaging

The European Union (EU) Falsified Medicines Directive (2011/62/EU) (FMD) was adopted in 2011 and introduced new harmonised measures to ensure that medicines in the EU are safe and that trade in medicines is properly controlled by providing protection to patients from falsified medicines in the legal supply chain of pharmaceuticals.

This will be achieved by verifying the product at point of dispense against a database.

Elements of the Directive have already been implemented. Member States have until 9 February 2019 to implement the final part of the Directive, the 'safety features' Regulation.

Under the Directive, secondary packaging of all new packs of prescription medicines placed on the market in Europe must bear two safety features: a unique identifier (UI) in the form of a 2D data matrix code and an anti-tamper device (ATD) allowing verification of whether the packaging of a medicinal product has been tampered. Human readable information will remain a feature of the packaging.

All Amgen packaging will be affected by the Falsified Medicines legislation. Amgen has therefore opted to transition its products in a phased approach. (Amgen has already implemented the anti-tampering device). This means that through 2018 the look and feel of the packaging of all Amgen products will change. (Below you will find an example of the changes.)

In the transition period up to February 9, 2019, test data will be uploaded to the verification database. During this period, verification of test packs may not be possible. In this circumstance verification of a pack remains the responsibility of the Pharmacist.

If you have any questions for Amgen about these changes, please contact commercial-team@amgen.com

Falsified Medicines Directive (2011/62/EU) implemented



Falsified Medicines Directive (2011/62/EU) not implemented



The serialized pack contains:

- **2D Barcode**
- **PC** = Product Code (GTIN)
- **SN** = Serialization Number
- **Exp** = Expiry Date
- **Lot** = Lot number
- **NN** = National Healthcare Reimbursement Number (if needed)

Note:

**Actual location of the different data elements and the 2D data matrix may change
2D matrix and unique codes will be printed on the packs in white**