Notifications of the safety features appearing on the packaging of medicinal products

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The new safety features have to be introduced in packaging of human medicinal products subject to prescription marketed in Finland as required in the Delegated Regulation of the European Commission (article 50 (EU) 2016/161) no later than 9th February 2019. Safety features consist of a package-specific unique identifier enabling the verification of the authenticity and identification of an individual package, as well as an anti-tampering device.

Addition of the unique identifier and the anti-tampering device (ATD) on the packaging of the medicinal products

When the addition of the safety features on the packaging of medicinal products changes the layout of the mock-ups, the marketing authorization holder should notify these changes to Fimea by a 90-day notification. Further information for the cases, when notification is not needed, can be seen on Fimea web-site “Safety features”.

According to the Commission Q&A Question 2.21 (version 12), the unique identifier should be printed on the packaging along with all other information required under article 54 of Directive 2001/83/EC (Article 5(3) of Commission Delegated Regulation (EU) 2016/161). Placing the unique identifier by means of stickers can be accepted in exceptional circumstances when no legal and/or technically feasible alternative exists or when competent national authority authorises it in the marketing authorisation or in specific circumstances to safeguard public health and ensure continued supply. The proposals to use stickers to add the unique identifier shall be notified to Fimea by a 90-day notification.

Addition of anti-tampering device on the packaging of OTC products and on the packaging of the medicinal products mentioned in the Annex I of the Commission Delegated Regulation 2016/161

If the ATD is placed or shall remain on the packaging of the medicinal products other than those required by the Commission Delegated Regulation 2016/161, the marketing authorization holder shall send a notification of them to Fimea by an e-mail to the address mrp@fimea.fi, with a subject “**Anti-tampering device**”. The e-mail notification should clearly identify the medicinal product (product name, strength and pharmaceutical dosage form) and the concerned package sizes.

The presence of multiple two-dimensional barcodes on the packaging

Medicinal products shall not bear on their packaging, for the purpose of their identification and verification of their authenticity, any other visible two- dimensional barcode (2D-code) than the 2D-code carrying the unique identifier (Article 9 of Commission Delegated Regulation 2016/161). If the packaging of a medicinal product contains 2D-codes for other purposes, these other 2D-codes should be clearly distinguished from the 2D-code carrying the unique identifier in order to avoid any confusion.

Ask more

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