Norwegian Medicines Agency

Oslo 25.06.2018

The warning triangle – implementation of a new practice

The Norwegian Ministry of Health and Care Services has given the Norwegian Medicine Agency (NoMA) the assignment to align the guidance for use of the warning triangle and the ability to drive, with the Norwegian regulation of the driving license, "førerkortforskriften".
All medicinal products for human use containing an active substance stated in the warning triangle list from the NoMA, shall bear the warning triangle. The requirement applies regardless of what type of procedure the medicinal product has been approved in.

The purpose is to harmonise the warning triangle guidance and Annex 1, chapter 14 § 36 in the regulation of the driving license "førerkortforskriften".

Which medicinal products shall bear the warning triangle?

The warning triangle list is based on the Norwegian Ministry of Health and Care Services' list of groups of medicinal products that may influence the ability to drive. The list is based on active substances. All human medicinal products containing one or more of these active substances shall bear the warning triangle on the packaging.
The warning triangle is a national Blue box requirement which must be included for all procedures.

Implementation

The changes must be implemented within 1.7.2019

The purely national procedure: The mock-ups can be updated in connection with a variation application which affects the mock-ups or a 61(3) notification for information can be submitted, provided that the warning triangle is added or deleted and no other changes to the layout has been made.

The mutual recognition procedure: The mock-ups can be updated in connection with a variation application which affects the mock-ups or a national 61(3) notification for information can be submitted, provided that the warning triangle is added or deleted and no other changes to the layout has been made.

The centralised procedure: The warning triangle is added or removed without an approval of the Blue box content from the NoMA. It is the MAHs responsibility to ensure that the changes are implemented as required. Do not submit a variation application to the EMA or the NoMA.

New medicinal products: The packaging of medicinal products containing active substance(s) included in the warning triangle list approved as of 1.7.2018, shall bear the warning triangle.

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The NoMA will evaluate whether new active substances shall bear the warning triangle during the procedure. If so, these will be added to the warning triangle list.

The applications can be submitted to: pi@noma.no

Warning triangle list, application form (notification 61(3), Q&A: http://bit.ly/2K2AeLm

Best regards

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