

8 September 2015

## **Fimea guidelines applicable in Finland to the advertising of medicines under additional monitoring**

### **The inverted black triangle and the accompanying standardised explanatory sentence**

The Finnish Medicines Agency Fimea requires that all marketing materials for medicinal products subject to additional monitoring under European Commission Regulation (EC) No 726/2004 (art. 23) display the symbol (inverted black triangle) specified in European Commission Regulation (EC) No 198/2013 and the accompanying, standardised explanatory sentence.

It is Fimea's view that the additional monitoring of medicinal products in accordance with the regulations referred to above, including the the relevant markings, represents information necessary to the correct and safe use of a medicinal product referred to in Section 91 a of the Medicines Act, and essential information on the medicinal product and its use referred to in Section 91 b of the Medicines Act.

The presentation of the inverted black triangle must comply with the specifications given in the Annex to regulation (EC No 198/2013), and each side must be at least 5mm long. Smaller triangles may not be used. The text of the explanatory sentence must be easy to read and proportionate to the size of the triangle, as indicated below. Both the triangle and the standardised explanatory sentence must be enlarged as required to make them proportionate to the font size used elsewhere in the material.

The inverted triangle is always black. No other colours are permitted.

The triangle and the accompanying standardised explanatory sentence must be separated from other text. The triangle and the sentence may not be separated from each other, nor should any other text or other elements be placed in their immediate vicinity. It is, however, permitted to add explanatory sentences used in the summary of product characteristics (This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. )after the standardised explanatory sentence.

The triangle is not to be part of the product logo.

In the case of electronic materials, the minimum recommendation is to place the black triangle and the explanatory sentence on the page on which the name of the medicinal product is displayed for the first time (usually the front page) and on the page containing product information, if this is a separate page. It is recommended that the same principle be followed in the case of other materials in which the product information is provided on a separate page.

The inverted black triangle and the standardised explanatory sentence are not required in any reminder advertisements for the medicinal products in question.

**Sample triangle and explanatory sentence:**

In Finnish: ▼ Tähän lääkkeeseen kohdistuu lisäseuranta.

In Swedish: ▼ Detta läkemedel är föremål för utökad övervakning.

In English: ▼ This medicinal product is subject to additional monitoring.

**Read more:**

[http://www.fimea.fi/aktuellit/meddelanden\\_om\\_lakemedelssakerhet/1/0/en\\_svart\\_triangel\\_m\\_ed\\_spetsen\\_nedat\\_berattar\\_att\\_lakemedlet\\_ar\\_foremal\\_for\\_utokad\\_overvakning](http://www.fimea.fi/aktuellit/meddelanden_om_lakemedelssakerhet/1/0/en_svart_triangel_m_ed_spetsen_nedat_berattar_att_lakemedlet_ar_foremal_for_utokad_overvakning)

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