COMMISSION IMPLEMENTING REGULATION (EU) No 198/2013

of 7 March 2013

on the selection of a symbol for the purpose of identifying medicinal products for human use that are subject to additional monitoring

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [1], and in particular Article 23(4) thereof,

Whereas:

(1) Some medicinal products for human use are authorised subject to additional monitoring for reasons of their specific safety profile. Pursuant to Article 23 of Regulation (EC) No 726/2004 this includes medicinal products with a new active substance, biological medicinal products and products for which post-authorisation data are required.

(2) Patients and healthcare professionals should be able to easily identify medicinal products that are subject to additional monitoring in order to allow them to share with the competent authorities and the marketing authorisation holder any information they have from the use of the medicinal product and in particular to report suspected adverse reactions.

(3) To ensure transparency, all medicinal products that are subject to additional monitoring are included in a list that is set up and maintained by the European Medicines Agency in accordance with Article 23(1) of Regulation (EC) No 726/2004. Additionally, they are labelled with a black symbol.

(4) On 3 October 2012 the Pharmacovigilance Risk Assessment Committee adopted a recommendation stating that the black symbol should be an inverted equilateral black triangle. The recommendation took into account the views of patients and healthcare professionals as expressed by the Patients' and Consumers' Working Party and the Healthcare Professionals' Working Group established by the European Medicines Agency.

(5) Holders of marketing authorisations that were granted before 1 September 2013 should be given sufficient time to adapt the product information of the products concerned.

(6) In addition, competent authorities should be given the possibility to grant a longer period of time for that adaptation where exceptional circumstances so require.

(7) The introduction of the black symbol should not cause difficulties on the market and in the supply chain. In order to avoid any disruptions, marketing authorisation holders should not be obliged to recall or repackage products which have been already placed on the market,

HAS ADOPTED THIS REGULATION:

Article 1

The black symbol referred to in Article 23(4) of Regulation (EC) No 726/2004 shall be an inverted equilateral triangle. It shall comply with the model and the dimensions set out in the Annex to this Regulation.

Article 2

1. Holders of marketing authorisations granted before 1 September 2013 which concern medicinal products for human use that are subject to additional monitoring shall include the black symbol in the summary of product characteristics and the package leaflet relating to these medicinal products by 31 December 2013.

2. By derogation from paragraph 1, holders of marketing authorisations granted before 1 September 2013 which concern medicinal products for human use that are subject to additional monitoring may request a longer period of time to be granted by the competent authorities, where they can demonstrate that compliance with the date referred to in paragraph 1 may unduly affect the appropriate and continued supply of the medicinal product.

Article 3

Stocks of human medicinal products produced, packaged and labelled before 1 January 2014, which do not include the black symbol in the package leaflet may continue to be placed on the market, distributed, dispensed, sold and used until stocks are exhausted.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

[1] OJ L 136, 30.4.2004, p. 1.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 7 March 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

1. The black symbol referred to in Article 23(4) of Regulation (EC) No 726/2004 shall comply with the following model:

2. The black symbol shall be proportional to the font size of the subsequent standardised text and each side of the triangle shall have a minimum length of 5 mm.