EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, EMA

COMMISSION DECISION
ON A "BLACK SYMBOL" IDENTIFYING MEDICINAL PRODUCTS FOR HUMAN USE THAT ARE SUBJECT TO ADDITIONAL MONITORING

TARGETED PUBLIC CONSULTATION ON
PHASING-IN REQUIREMENTS

DEADLINE FOR PUBLIC CONSULTATION: 10 JANUARY 2013

This document does not represent an official position of the European Commission. It is a tool to explore the views of interested parties on a preliminary draft. The suggestions contained in this document do not prejudge the form and content of any future proposal by the European Commission.

CONTACT:

Responses should be sent preferably by e-mail to sanco-pharmaceuticals-D5@ec.europa.eu, or by post to Directorate-General for Health and Consumers, Unit SANCO/D5, BE-1049 Brussels. The subject of the letter/e-mail should refer to "PCBSM/12/01 - Public Consultation on the phasing-in of the black symbol".

1. INTRODUCTION

Under the new pharmacovigilance provisions some medicinal products for human use are authorised subject to additional monitoring for reasons of their specific safety profile.

In accordance with Article 23(5) of Regulation (EC) No 726/2004 all products that are subject to additional monitoring shall contain in the summary of product characteristics and the package leaflet the statement 'This medicinal product is subject to additional monitoring'. That statement shall be preceded by a black symbol.

The black symbol shall be selected by the Commission following a recommendation of the Pharmacovigilance Risk Assessment Committee.

In the context of selecting the symbol the Commission is currently considering the arrangements for the inclusion of the symbol in the summary of product characteristics and the package leaflet of all products concerned.

This concept paper is being rolled out for public consultation with a view of receiving feedback from stakeholders on this issue.

The adoption of the decision selecting the black symbol is scheduled for 2013.

2. CONSULTATION TOPICS

2.1. Adaption of product information to new requirements

Additional monitoring is one of the key public health deliverables of the new pharmacovigilance legislation and a quick uptake of the symbol is considered important in order to achieve its goals. This includes the need to make healthcare professionals and patients aware of the products that are subject to additional monitoring in order to trigger a more targeted supervision of such products and directly involve them in the reporting of specific observations they make when using the product.

Without the symbol healthcare professionals and patients may miss this information. Hence, the symbol is an important communication and awareness-rising tool.

It is recognised that pharmaceutical companies may need a certain amount of time in order to comply with the new requirement. This applies especially to products that are already authorised and fall within the scope of the additional monitoring requirements. For those products companies have to adapt the package leaflet and print new versions. Moreover, modification of the content of the package leaflet and the summary of product characteristics is subject to a regulatory procedure by means of a variation.

It is therefore necessary to balance the public health interest with the practical and operational limitations of pharmaceutical companies.

In this context the Commission is currently considering the practicalities of adapting the existing product information to the new requirements, in particular the time needed by companies to adapt the relevant product information to include the black symbol.

The Commission would kindly invite stakeholders to comment on how much time a marketing authorisation holder needs to adapt and print the updated product information (summary of product characteristics and patient leaflet).

Consultation item No 1: Please comment on the time needed for the preparation and printing of the updated product information. How many weeks would be appropriate?

2.2. Products packaged before the decision on the identification of the black symbol

The Commission would like to understand the potential impact of the change in product information on stocks of medicinal products held by the marketing authorisation holder before certified batches are being released to the supply chain. Therefore, the Commission would like information on how long stocks of packaged medicinal products that include the patient information leaflet are held by marketing authorisation holders after packaging and before being released for sale and supply.

Consultation item No 2: How long are stocks of medicinal products packaged with the product information held by the marketing authorisation holder (or the responsible manufacturer) before being released for sale and supply?

* * *

Stakeholders are invited to comment on this consultation paper, by replying to the two questions in the boxed text, by 10 January 2013 at the latest. Responses should be sent (preferably by e-mail) to sanco-pharmaceuticals-D5@ec.europa.eu, or by post to Directorate-General for Health and Consumers, Unit SANCO/D/5, BE-1049 Brussels. The subject line of the letter or e-mail should refer to 'PCBSM/12/01 - Public Consultation on the phasing-in of the black symbol'.

When you send your comments and responses, you should state whether you are a stakeholder association or a private individual. If you represent an association, please indicate clearly what type of association it is (patients, health professionals, manufacturers, marketing authorisation holders, etc.). If you represent a company, please state whether it falls within the EU definition of a small and medium-sized enterprise (i.e. less than €50 million annual turnover and fewer than 250 employees).

An acknowledgement of receipt will be issued for each contribution received.

The contributions received and the identity of the contributors will be made publicly available on the 'public health' website[1], unless the contributor objects to the publication of his or her personal data on the grounds that it would harm his or her legitimate interests. In this case the contribution may be published in anonymous form. Otherwise the contribution will not be published nor will, in principle, its content be taken into account. For more information on the processing of your personal data in the context of this consultation, you should read the specific Privacy Statement available on the public health website.

Professional organisations are invited to register in the Union's Register of Interest Representatives (http://europa.eu/transparency-register/index_en.htm) set up as part of the European Transparency Initiative to provide the Commission and the public at large with information about the objectives, funding and structures of interest representatives.

[1] http://ec.europa.eu/health/human-use/index_en.htm.