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Re. PCBSM/12/01 - Public Consultation on the phasing-in of the black symbol

Concept Paper on the

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 (Ref. Ares(2012)1374449)

EUCOPE Comments

The European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) represents via national member associations, including BPI (Germany), EMIG (UK), SwedenBio (Sweden) and the US Biotechnology Industry Organization (BIO) more than 900 mid-sized innovative - often family owned - pharmaceutical and biotech companies. In addition, many innovative companies from Austria, Bulgaria, France, Germany, Greece, Italy, the Netherlands, Sweden, and the UK are represented on the board of the association. EUCOPE membership includes innovative family owned companies such as B.Braun, Sigma-Tau, Ferring, Miltenyi or Vianex as well as innovative companies active in the field of biotechnology and rare diseases such as Alexion, Celgene, InterMune, Otsuka or Grifols (www.eucope.org).

EUCOPE appreciates the opportunity to comment on the above mentioned Concept Paper. In general, we agree with the draft, however, we see the need to allow for sufficient timelines for companies to adjust to the new requirements foreseen in Art. 23(5) of Regulation (EC) No 726/2004.

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?

First and foremost, the **timelines depend on the duration of the necessary procedures involved at the regulatory authorities, e.g. for the variations**. Furthermore, decisive factors which determine the time needed to update the product information, the preparation and the printing could be the size of the company and the volume of different products sold by the company. Especially companies with a big product portfolio might be concerned most.

Taking into account the above mentioned aspects each revision regarding the implementation of the black symbol in SmPCs and PILs will need **a time period of 4 months to up to 1 year** due to capacity reasons.

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?

The storage of medicinal products packaged with the product information at the marketing authorization holder (MAH) / manufacturer depends on the shelf-life and stability of the product. Furthermore, the market demand for the product as well as the size of (bulk) charge play a decisive role. The storage time depends also on the fact whether a product is produced and labeled at the own plant (which will take less time) or if a product is produced and labeled at subcontractors' plants (which will take more time).

It needs to be kept in mind that for some products, e.g. vaccines, the time for being released for sale and supply is very short (sometimes less than one day).

Usually companies have a stock sufficient to cover a time period of 1/2 to 1 year or 2 years. Therefore, from our point of view a transitional period of **two years** for the MAH would be adequate.

Furthermore, **transitional timelines should be foreseen due to the fact that products have been released to the market already and still regulatory aspects about the black symbol are still not decided yet.** In case that an exchange for already released products would be required, all products have to be sent back to the manufacturing site. The transfer can be required in a temperature controlled manner (e.g. cold chain or even deep-frozen). This would cause a tremendous burden for the companies. In addition, this could cause out of stock situations, new batch numbers and new batch releases (in case of biological products also from the Official Medicines Control Laboratories (OMCLs)). In cases of deep-frozen products, an exchange of the packaging is not possible. Generally, it should be possible to sell all products in the form already released to the market.

For the reasons stated above, EUCOPE urges the Commission to set sufficient timelines in the Decision on the "Black Symbol".

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