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Comments

To: European Commission, sanco-pharmaceuticals-D5@ec.europa.eu

From: German Pharmaceutical Industry Association (BPI),
Dr. Boris Thurisch (Head of Pharmacovigilance)
Matthias Heck (EU Policy and Legal Advisor)

CC:

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

Date: 10.01.2012

Comments of Bundesverband der Pharmazeutischen Industrie e. V. (BPI) - German Pharmaceutical Industry Association concerning the Draft "Commission Decision on a "Black Symbol" Identifying Medical Products for Human Use that are subject to Additional Monitoring"

01/10/2012

BPI appreciates the opportunity to review and comment on the above mentioned Concept paper. In general we agree with the draft, however, we see the need to take into account the following general points:

(A) General comments:

(1) Repacking

Normally a released product is directly sent to the country warehouses, which has no permission to repack products. In case that repackaging would be required, all products have to be sent back to the manufacturing site in a

temperature controlled manner (e.g. cold chain or even deep-frozen). This would cause a tremendous burden for the companies. In addition, repackaging 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)). Please bear in mind that products, which are kept deep-frozen cannot be repacked.

(2) Inverted Black Triangle

Due to the fact that the inverted black triangle is assumed as black symbol like in UK, consumer could be confused since the similar established symbols are also use in some Member States (e.g. for toxic substances). Furthermore, it does not suggest the action of “monitoring”. Therefore our suggestion is to discuss an alternative symbol, like a magnifying glass.

(3) Implementation of the Black Symbol

It is highly recommended to implement the black symbol simultaneously with the additional instruction of the adverse reaction notification in SmPCs and PILs to avoid unnecessary expenditure. Therefore a black symbol related product list is deemed necessary.

(4) Processes

It has generally be taken into account how the decisions and processes will be to determine and communicate that a product is "subject to additional monitoring" and - perhaps after a certain interval - is a "product not any more subject to additional monitoring" to avoid a "back and forth"-situation of products with incalculable expenditure of time and costs for the marketing authorisation holder (MAH).

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(B) Specific comments:

In the following part of this position, the BPI will answer the consultation items the Commission raised in the concept paper.

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?

The time frame for the artwork creation, preparation and printing of the updated product information depends mainly on the bureaucracy and the organizational structure as well as the size of the company. The more employees are involved in the process (e.g. review, internal approval, submission of a concerned variation), the more time will be needed. Furthermore, if partners or affiliates are involved in the process (for example in the case of a product with global licenses), also more time is needed. Often in these processes conditions of regulatory authorities - like regulatory approval - can be a crucial factor influencing timelines.

Taking into account the above mentioned aspects each revision regarding the implementation of the black symbol in SmPCs and PILs will need **a minimum time period of 4 months** until new package material is available, provided that only centrally approved pharmaceuticals subject to a risk management plan are affected. If more products are affected implementation would take more time (**up to 1 year**) due to capacity issues.

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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 MAH/ manufacturer depends on the shelf-life and stability of the product. That means that products with a long total shelf-life, can be kept for longer in stock before being released for sale and supply. Furthermore, the market demand for the product as well as the size of (bulk) charge play a decisive role. The time depends also on the fact whether a product is produced and labelled in the own plant (which will take less time) or if a product is produced and labelled at subcontractors' plants (which will take more time). As mentioned the general part (A), it needs to be kept in mind that some products are directly sent to the country warehouse (e.g. vaccines). In those cases 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 half to one year. Therefore, from our point of view a transitional period of **two years** for the pharmaceutical entrepreneur would be adequate as well as the possibility to completely sell the stock of packages which are already marketed.Berlin, 10th January 2013