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European Commission
Directorate-General for Health and Consumers
Unit SANCO/D5
BE-1049 Brussels
Submitted via email sanco-pharmaceuticals-D5@ec.europa.eu

9 January 2013

Re: Public consultation on the phasing-in of the black symbol

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Madison, NJ 07940
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Dear Sir or Madam:

Reference is made to Ares(2012)1374449-21/11/2012 whereby the European Commission requested comments 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.

Bausch + Lomb is one of the best-known and most respected healthcare companies in the world. Our core businesses include contact lenses and lens care products, ophthalmic surgical devices and instruments, and ophthalmic pharmaceuticals. Founded in 1853, our company is headquartered in Rochester, N.Y., and employs more than 10,000 people worldwide. Our products are available in more than 100 countries. Bausch + Lomb is committed to ensuring the safety of our products and the timely implementation of important changes to product labeling.

Bausch + Lomb appreciates the opportunity to provide our feedback and experience on the timing for revision of product information. Towards that end, we offer the following general and specific comments.

GENERAL COMMENTS

In our specific comments below, we provide feedback based on our current experience and wish to emphasize that revisions to product information can include many considerations such as ordering new materials, changes in equipment to accommodate a new product information configuration[1], associated line testing, continuity in the supply chain, timing based on the

[1] As noted in this concept paper, the selection of the symbol (including size and specific location) for inclusion in the summary of product characteristics and the package leaflet has not yet been selected.

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regulatory procedure for a labeling variation, etc. As such, a change to the product information may be simple or multifaceted.

In addition, there should be a reasonable time allotted for a coordinated and "rolling" implementation necessary to convert the product information into each individual country language (e.g., for a product approved via MRP). Bausch + Lomb requests that the draft guideline address this strategic matter and include recommendations on expectations regarding prioritization (e.g., based on sales volume).

SPECIFIC FEEDBACK IN RESPONSE TO CONSULTATION QUESTIONS

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?

Addition of information to the product information (can result in a change to the layout and/or fold of that component. Specifically, addition of the black symbol to the product information may result in a new layout/fold based on the current layout and size/location of the black symbol. The manufacturer may need to assess if the current folding equipment can accommodate a larger or expanded patient leaflet.

In addition, drug product cartons are precisely designed for packaging the drug product and accompanying product information. A change to the patient leaflet specification can effect a change in the carton specification (e.g., larger carton, new seal location).

Each of these examples may require line trials to assess current equipment capabilities. These line trials must typically be scheduled into an already established production schedule. Scheduling a line trial must be balanced with limiting disruptions of product supply for other important prescription medicines. Scheduling for products manufactured and/or packaged by a contract manufacturer may also require additional planning based on current scheduling for other companies, terms of the contract, etc.

With the above taken into consideration, we have experienced the following general timeframes:

- Revision of product information: 6 weeks
- Scheduling of line to test: an additional 4 – 16 weeks
- Overall time when a line test is needed: 6 – 24 to 32 weeks

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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?

In some instances, a product may need to be reworked to incorporate new labeling. In these situations, additional time may be associated with recovering existing stock i.e., a batch not yet in public distribution but stored in a distribution center. Return of product still within the company's control may take as little as 1 – 3 weeks. However if the product has been shipped to a distribution center outside of the company's control, it could take up to 6 months to return the product. Furthermore, product temperature storage conditions need to be considered for reworked/relabeled products (i.e., room temperature versus cold storage). Rework of a temperature-sensitive product may require additional time to execute.

Also to be considered is the frequency of manufacturing the product. Based on demand, expiration date, and other considerations, some products may only be manufactured periodically (e.g., every 2 years) while other high volume products may be manufactured daily. Bausch + Lomb cautions the Commission in developing timeframes which may inadvertently imply that a batch must be manufactured to implement this change.

Bausch + Lomb appreciates the opportunity to provide feedback and trust these comments will contribute to an enhanced understanding of the product information revision processes and timing considerations.

Sincerely,

Kimberly Belsky
Executive Director, Global Pharmaceutical Regulatory Affairs