Making Medicines Affordable

Directorate-General for Health and Consumers

Unit SANCO/D5

BE-1049 Brussels

Brussels, 10 January 2013

Reference: **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**

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?

There is no consideration in the Decision document about whether the new artwork would need any agency approval. If required, this would need additional time for generation, submission and review of new mock ups and/or specimens. This process (excluding formal agency review) needs to be clarified in order to make an accurate assessment of the time needed to prepare the materials. After approval, up to 6 months would be needed for preparing artworks and printing for the new packaging materials. Furthermore, supplies of packaging material are very often held in stock. To avoid the destruction of any existing material and the ensuing financial implications, **12 months should be considered.**

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?
Technically speaking a product is sold until 6 months prior to the end of shelf life. Companies should be allowed to sell out existing stocks, otherwise write-off costs will be significant.
This is important in particular for products where repackaging would not be possible i.e. for products under special storage conditions or in special packages (e.g. cool chain conditions or blistered and sealed packs). Destroying the finished goods would have a great financial impact and must be avoided.

In general, Stock Keeping Unit (SKU) level stocks vary from 1 month to 12 months due to demand volatility and supply chain parameters (batch sizes, production frequency, minimum order quantities, lead times etc.)

General Comment and Consideration
By subjecting biosimilar medicines, authorised after 1 January 2011, to additional monitoring and to carrying the black symbol on their label without any special safety reasons, while not requiring the same of their reference product, authorised before 1 January 2011, will put an undue and unfair burden on the biosimilar products which is not based on science because biosimilar products are explicitly approved as equally safe and effective as their reference products.
Taking the new legal obligation into account, it is paramount that the balance is restored by requiring the additional monitoring to all biologics, authorised before 1 January 2011, that have been subject to

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significant manufacturing changes, as defined by the need to demonstrate the unaltered safety and efficacy of the post-change product in animal studies or human clinical studies.

The legislation does not appear to take into account that a biologic, that has gone through a manufacturing change significant enough that the unaltered safety and efficacy of the post-change product needs to be confirmed in animal studies or human clinical studies, **may in effect result in differences larger than those found in a biosimilar and should consequently also be subject to additional monitoring.**
This approach will as well help increase the understanding of doctors and patients of the complexities of biologics. It would also help in levelling the playing field for biosimilar medicines, and counter possible misinformation based on this new legal requirement.

Yours faithfully,

On behalf of the EGA-EBG (European Biosimilars Group), a sector group of the EGA
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