AESGP
Association Européenne des Spécialités Pharmaceutiques Grand Public
Association of the European Self-Medication Industry
Europäischer Verband der Arzneimittel-Hersteller

AESGP COMMENTS ON THE EUROPEAN COMMISSION'S PUBLIC CONSULTATION ON PHASING-IN REQUIREMENTS ON A BLACK SYMBOL IDENTIFYING MEDICINAL PRODUCTS SUBJECT TO ADDITIONAL MONITORING

AESGP represents the manufacturers of non-prescription medicines of either chemical or herbal origin at European level. It counts 29 national associations and 25 associate members. Through its national and associate members, it represents many small and medium-sized companies operating in the self-care sector.

AESGP appreciates the opportunity to take part in this very important consultation.

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

Managing the supply chain for packaging changes is complex as it not only depends on the preparation/printing of the packaging material but also on the type of product, the turnover as well as the shelf life. In addition, time needed to implement a change also depends on the number of affected Stock Keeping Units (SKUs).

The average time to implement a change on printed packaging components is 9 months. This is the time needed from initiation of the text change until goods are produced with the updated packaging material.

For countries with a need to register artworks, this can take longer – more than 2 years in case the authority requests to change the artwork.

Consultation item No 2 – Products packaged before the decision on the identification of the black symbol
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 average time from Quality Assurance (QA) release in the production site until the finished product with the change implemented reaches the consumer by the supply chain is approximately 3-5 months. This includes QA release time, transportation, custom clearance and stock in the countries.

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It has to be noted that there is a need to maintain safety stock in the countries to ensure adequate stocks area available to supply the market. This should be considered in addition to stock held prior to release into the supply chain.

Furthermore it has to be taken into consideration that some products might have a very low turn-over of up to 52 weeks depending on the country and the extent of use.

To give one example: seasonal products, e.g. cough/cold (winter) or hayfever (summer), have the potential to take longer to sell as the season can be unpredictable in terms of cough/cold incidence and the summer pollen count. The manufacturer therefore always has to ensure there are enough products to avoid an out of stock, but in a "low volume" season, this may result in the product being produced and not shipped until the following season.

From an Industry point of view, we would appreciate clear guidance and a long grace period in order to be able to combine the implementation of the symbol together with other changes.

It would be highly appreciated if there is consensus that goods already on the market without the black triangle do not have to be re-called or re-packaged.

10 January 2013