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Commission Decision on a "Black Symbol" identifying medicinal products for human use that are subject to additional monitoring

EFPIA COMMENTS

Comments from:

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Introduction

EFPIA response
EFPIA/EBE/Vaccines Europe welcome the opportunity to provide feedback to the targeted public consultation on phasing-in requirements for the black symbol: The logistics of managing the supply chain to accommodate packaging changes is complex and highly variable depending mainly on the type of product, its turnover and shelf life, but also on the number of manufacturing sites involved in labelling and packaging, stability of the demand, the supply variability, the manufacturing site capacity constraints, the cost efficiency factors, etc. Very often products are available as multiple presentations (strength and pack size combinations) thus there is a need to manage the stocks of each presentation in each EU market. Turnover, for example, can clearly be variable depending on the individual country and the extent of usage of the product. Shelf life is an important consideration in determining how long stocks can be held before release onto the market. Furthermore, many biological products require maintenance of the cold chain which presents an additional logistical challenge for storage. The management of stock and the introduction of packaging changes is a particular challenge for companies with large product portfolios in many European countries, due to the large volume of affected artworks. In view of the number and type of variables at play and the over-riding public health need to minimize any risks of shortages of product to patients, pharmaceutical companies need to have flexibility to introduce revised packaging into the marketplace. Experience across multiple companies indicates that at least 6 to 12 months from regulatory approval of the change is required to begin to introduce the revised product packaging into the supply chain to the warehouse, and then the timelines at the warehouse have to be taken into consideration for the product with the revised packaging information to reach the market. In this respect, it is important to underline that supply disruption would be avoided if products already on the market, without the black symbol, will not have to be recalled or repackaged, and if the existing stocks in the supply chain can be used until exhausted. ***Please see to the process chart below.***

Black symbol Labelling update

Authority/ Company

- Submission
- approval
- Country translations

Timeline:
up to 6 month
(depending on the procedure)

Production Labelling

Process start

- Approval Labelling update

Production Batch

Process

- Printing of PIL (Batch Production)
- Pack of batch
- Shipment to warehouse

Timeline: up to12 month
"Combination of small and large change of PILs"

Warehouse

Process

- Store of batch
- Ship to country warehouse
- Distribute to wholesaler

Timeline,
based on several factors including:
Shelf life
Order size
Turnover high / low
(see table in item 2)

Costumer

Process

- Receiving shipment

Consultation item N°1:

Please comment on the time needed for the preparation and printing of the updated product information. How many weeks would be appropriate?

	EFPIA response
	In general, depending on the product and other factors, a period of up to 26 weeks after approval of the updated product information might be appropriate for the preparation and printing of the updated product information (i.e. for the updated leaflets to be available at the manufacturing site, ready to be used on the next packaging run). However, in total, up to 52 weeks after approval of the updated product information could be needed for introduction of the revised product packaging into the supply chain to the warehouse in some cases. ***Please see attached process chart above, which is explaining the situation.*** We would like to emphasise that the above timeline will not be applicable to all products, and that the number of weeks can vary significantly depending on several factors. These factors include the volume of leaflets to be changed at any one time (number of products, strengths and presentations impacted) and the capacity at the printed packaging development department (due to other changes, holiday breaks, etc.) which adds to the complexity. These could as well increase implementation timelines. Please take additionally into consideration certain seasonal products, e.g. flu vaccines, which may have specific timing considerations. In some cases, activities to support packaging need to begin in early Q1, and the adoption of the black symbol and associated QRD template changes after this time may impact availability of product at the beginning of the next season.

Consultation item N°2:

How long are stocks of medicinal products packaged with the product information held by the marketing authorization holder (or the responsible manufacturer) before being released for sale and supply?

	EFPIA response
	How long the stocks are being held by the marketing authorization holder depends on the turnover, shelf-life and the type of product. It is important to note that other variables could also impact the inventory levels of packaged medicinal products held by the marketing authorization holders after packaging and before being released for sale and supply for them: the stability of the demand, the supply variability, the manufacturing site capacity constraints and the cost efficiency factors (like those associated to shipment). Given the high degree of variability and the need for flexibility, the worst-case scenario should be taken into account. ***Please refer to the table below***, which illustrates possible ranges of storage time based on the high or low turnover considering the main variables (i.e. shelf life and type of product). These periods should be taken into account, allowing companies to run through existing stocks in order to minimise the risk of interruptions to supply for patients, to avoid unnecessary and wasteful write-offs and to facilitate planned introduction of new product information.

Ranges of storage time (in weeks) of different types of medicinal products		
turnover	high	from a minimum of 4 to 30 weeks onwards
	low	from 24 to 72+ weeks