

EuropaBIO comments on

PHASING-IN REQUIREMENTS - COMMISSION DECISION ON A "BLACK SYMBOL" IDENTIFYING MEDICINAL PRODUCTS FOR HUMAN USE THAT ARE SUBJECT TO ADDITIONAL MONITORING

General comments

EuropaBio would like to stress that the exact time needed to prepare for the new system will depend on the final requirements and the final lists of products which will be subject to additional monitoring. Due to this uncertainty, there is a need for a flexible approach to allow smooth phasing-in without any supply disruptions or unnecessary disposal packaged products with existing artwork. It is also important to consider specific needs of certain products, such as biological products. It is very complex to manage the supply chain to accommodate packaging changes and it depends on many factors, such as the type of product, its shelf life, the actual stock in a specific country, etc.

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?

In general, 6 months could be appropriate for preparation and printing of the updated product information. However, it is important to note that companies with larger product portfolio of affected products might need longer timelines due to the large volume of affected artwork. For those companies 12 months implementation timeline would be more appropriate due to complex planning and logistics.

Consultatio 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?

This depends on various factors, including the type of product, its shelf life, the country where the product is shipped to, and what the actual stock is in that country. In general, a maximum of an additional 18 months for sale and supply to consume the current stock, especially in smaller markets with low turn-over products, would be needed. In this context, EuropaBio would also like to highlight that new rules should ensure that companies are able to consume their existing stocks.

About EuropaBio

EuropaBio, the European Association for Bioindustries, brings together bioscience companies from all fields of research and development, testing, manufacturing and distribution of biotechnology products, including biopharmaceuticals. It has 56 corporate and 14 associate members and 19 national biotechnology associations - representing some 1800 small and medium sized enterprises across Europe.