

From: Jane

To: SANCO PHARMACEUTICALS D5

Subject: PCBSM/12/01 - Public Consultation on the phasing-in of the black symbol

Dear Sir/Madam

I am writing on behalf of the European Industrial Pharmacists' Group which is a professional organisation representing 12,000 industrial pharmacists in the European Union.

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?

Response: The average time to prepare and print an updated leaflet is 3-5 months. This time can be reduced if the amendment is an urgent safety update.

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?

Response: About 6 months is required from a decision to amend the leaflet to release of the first production batch containing the new leaflet. To this should be added 3-4 months to exhaust the remaining stock of the product.

Therefore a lead time of 1 year from decision to product release is recommended. If the amendment is an urgent safety restriction, the lead time should be considered on a case by case basis.

Yours faithfully

Jane Nicholson BPharm.FRPharm.S.FTOPRA
Executive Director EIPG