From: Sander Michael
To: SANCO PHARMACEUTICALS D5
Subject: PHARMIG comments on "PCBSM/12/01 - Public Consultation on the phasing-in of the black symbol"

Dear Sir or Madam,

PHARMIG, the association of the Austrian pharmaceutical industry, would like to thank for the opportunity to comment on the TARGETED PUBLIC CONSULTATION ON PHASING-IN REQUIREMENTS .

We have 120 members based in Austria and Germany and operating worldwide. The products of our members represent nearly 100 percent of the Austrian pharmaceutical market. Our members have ca. 10,000 employees.

Please find our comments following.

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?

>> Based on a survey amongst our members a standard lead time up to 12 weeks is required for the preparation and printing of the updated product information.

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?

>> There is no standard. This depends on the product, the shipping destination (country) and the actual stock at the respective destination. A maximum of six months is required for consuming the current stock, especially in smaller markets and with products with a slow turnover.

Kind regards
Michael Sander

Mag. (FH) Michael Sander

Senior Advisor Regulatory Affairs, Pharmacovigilance & Distribution

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