From:

To: SANCO PHARMACEUTICALS D5

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

Dear Sir/Madam,

I am responding to the questions below on behalf of Pharmaxis Pharmaceuticals Limited (company) which currently holds SME status. Please do not publish my personal details but instead use the company details as the source of these responses.

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 order to complete all the steps required this would take up to 7 weeks not including any variation application timelines which may be required.

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?

A stock inventory of up to 7 months is held by the MA holder/responsible manufacturer.

Kind regards



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## **IMPORTANT**

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