From: Thalassaemia International Federation - LC
To: SANCO PHARMACEUTICALS D5
Subject: PCBSM/12/01 - Public Consultation on the phasing-in of the black symbol

January 2013

TO WHOM IT MAY CONCERN

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

On behalf of the Board of Directors of the Thalassaemia International Federation we would like via this communication to state our views on the above-mentioned subject.

Allow me to briefly introduce our Federation:

The Thalassaemia International Federation (TIF) was established in 1986 as a patients and parents organisation with the mission to promote the quality of health care and quality of life of patients with thalassaemia. Since 1996, TIF has been in official relations with the World Health Organisation (WHO) and is considered to-date the international reference organisation for Haemoglobin disorders with more than 110 national thalassaemia associations from 60 countries of the world under its umbrella.

Expressing great enthusiasm for the revision and implementation of a new pharmacovigilance legislation, we further applaud the use of a distinct symbol to inform consumers of products that are subject to additional monitoring. We do however realise that this will undoubtedly incur additional costs for pharmaceutical companies, especially when amending package leaflets to comply with the new legislation. Nevertheless, the black symbol will increase transparency and guarantee the rights of consumers.

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?

For each product, an upper time limit of 6 – 8 weeks should be given to pharmaceutical companies to prepare and printing the updated product information. This will mean that products will reach consumers with the most updated information available.

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?

This Consultation item is better to be answered by stakeholders who are more knowledgeable to the levels of stock that are produced and stored by pharmaceutical companies.

We look forward to the implementation of this measure.

Sincerely,

Thalassaemia International Federation

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