From: Ondrušová Stela [mailto:Stela.Ondrusova@health.gov.sk]
Sent: Wednesday, March 19, 2014 10:45 AM
To: SANCO PHARMACEUTICALS D5
Cc: Slaný Jozef; Kovácsová Šárka; maria.brozmanova@mzv.sk
Subject: FW: External study on the availability of medicinal products for human use
Importance: High

Dear Madam or Sir,

With reference to your two questions regarding the External study on availability of medicinal products for human use, there are the answers of Slovak Republic:

1. **To provide us with your comments on this study report, in terms of the correctness of the analysis and applicability of the findings to your national situation**

Slovak Republic has no comments to the Study on the Availability of Medicinal Products for Human Use. The study provides an overview of the procedures for placing medicinal products on the EU market and accurately identifies the most common and the most fundamental causes of unavailability of medicinal product for human use, either on the single European market or on the individual EU Member State market.

The study correctly states that in Slovak Republic the shortage of certain medicinal products causes parallel exports.

Slovak Republic applies the External Price Referencing (EPR) when deciding on the inclusion of the medicinal products to the list of categorized medicinal products. When applying the External Price Referencing (EPR) we use the European reference price of medicinal product. This criterion is in accordance with Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems, because it is objective and verifiable.

European medicinal product reference price is the average of the three lowest prices among the officially designated medicinal product prices in other Member States.

If the product has officially determined price in one of the other Member States, officially designated medicinal product price in this country is considered as the European reference price of the medicinal product.

If the product has officially determined price in two other Member States, the European reference price of medicinal product is the average price of medicinal product in these two Member States.

To ensure availability of medicinal products, we consider as very important the provision of Article 5, paragraph 1 of Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use. We share the view that it is a "life saver article". We recommend to extend its scope to the group of patients.

Slovak Republic does not apply provisions of Article 126a of Directive 2001/83/EC, as well as the provision of Article 83 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. These provisions are transposed into Slovak legislation, although we do not apply them, as we consider them administratively cumbersome and lengthy for urgent cases. Therefore, we recommend their simplification to be applicable in real-time upon the provision of healthcare.

In Slovak Republic, in case of unavailability of medicinal product due to that medicinal product does not have required valid registration, we use Article 5.1 of Directive 2001/83/EC.

To send us an updated list of all products authorised under Article 126a of Directive 2001/83/EC.

In Slovak Republic we have not issued a permit pursuant to Article 126a of Directive 2001/83/EC.

Kind regards,

Mgr. et Mgr. Stela Ondrušová

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