From: Sergejs.Akulics@zva.gov.lv [mailto:Sergejs.Akulics@zva.gov.lv]
Sent: Thursday, March 13, 2014 10:58 AM
To: SANCO PHARMACEUTICALS D5
Cc: Elma.Gailite@zva.gov.lv; Dace.Kikute@zva.gov.lv; Inguna.Adovica@zva.gov.lv
Subject: Re: External study on the availability of medicinal products for human use

Dear Sirs,

In reply to your letter (received by the State Agency of Medicines of Latvia on 25 February, 2014 (reg. No 1842/1-4) we would like to inform you that there are seven medicinal products authorised under Article 126a of Directive 2001/83/EC in the Republic of Latvia (please see attachment). Detailed information on medicinal products is available in on our web page - http://www.zva.gov.lv/?id=513&lang=&top=112&sa=377.

We have found in your report some inaccuracies and we would appreciate if you correct them. We noticed incorrect information regarding applicability of the Common Baltic Package. This procedure applies to medicinal products authorised via National Procedure without time restriction. It could be used also for medicinal products that are authorised after 1 May, 2004 (for example for line extension application). The correct sentence could be:

On page 85
According to the stakeholder consultation, the procedure applies to medicinal products authorised via National Procedure. ~~before 1 May 2004.~~

On page 88
Although the applicability of the Common Baltic Package procedure is somewhat narrow ~~(it only applies to products authorised nationally prior to 2004)~~ the experience of national competent authorities in Latvia, Estonia and Lithuania is a positive one, since the procedure is seen as helpful in tackling availability problems.

Do not hesitate to contact us in case of further questions appear.

Sincerely yours
Sergejs Akulics
Department of Information on Medicines Distribution
Deputy Head

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