Ravimiamet
State Agency of Medicines

European Commission
DG Health and Consumers

Sent by e-mail to:
SANCO-PHARMACEUTICALS-D5@ec.europa.eu

April 29, 2014
No JUR-1/3482-3

Re: External study on the availability of medicinal products for human use

Dear Sir or Madam,

State Agency of Medicines appreciates the initiative on the availability of medicinal products for human use within the EU and welcomes the study report of Matrix Insight as the report covers important problems regarding public health in the EU Member States.

However, State Agency of Medicines would like to stress the incorrect quotations from the HMA report from 2007 of the Common Baltic Package procedure which is applicable in Baltic States. Report of Matrix Insight states that: "According to the stakeholder consultation, the procedure applies to medicinal products authorised via National Procedure before 1 May 2004." (p 85).

We would like to clarify that the Common Baltic Package procedure is completely voluntary procedure for Marketing Authorisation Applicant. The procedure may be used for all medicinal products authorised in Estonia, Latvia and Lithuania either in National Procedure (NP), Mutual Recognition Procedure (MRP) or Decentralised Procedure (DCP) not depending on the time of the issue of the marketing authorisation or the type of the procedure. The procedure is highly recommended by the Baltic Agencies as it helps to avoid the availability issues due to the lack of packages in official language.

We kindly ask you to correct the above-mentioned mistakes in the report before publishing it.

We would also like to draw the attention that for medicinal products in Centralised Procedure, the Applicant of Marketing Authorisation should to consider the possible combination of official languages for multilingual packages (e.g. Baltic package) already in the Marketing Authorisation procedure or even before the submission of the Marketing Authorisation Application. Also the possibility of use of stickers (re-labelling) to comply with the official language requirements should be considered before the Marketing Authorisation will be granted as the later addition of the manufacturing site via variation procedure could delay the availability.

Regarding to the offered solutions in the report we are of the opinion that many of those could solve the availability problems but we do hesitate if these steps will ensure the availability of medicinal products in the future. First of all, we see the proposed solutions as unsustainable if the

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solution for "financially not interesting and small markets" would be only regulating the exemptions from the essential rules meant to guarantee health of patients in the EU (e.g. drug information in local official language). According to the proposed solutions we are building the double-standards for the EU patients depending on the country. Secondly, the idea to offer industry the incentives as proposed in the report is worth to discuss but the discussion should be balanced with the obligations on industry about the availability medicinal products. We are happy to participate in these discussions with the EU Commission.

Yours sincerely,

Kristin Raudsepp
Director General
Estonian Representative of the Pharmaceutical Committee (Human)

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