From: Anela Kraljević [mailto:Anela.Kraljevic@halmed.hr]
Sent: Friday, March 21, 2014 5:00 PM
To: SANCO PHARMACEUTICALS D5
Cc: Viola Macolić-Šarinić; Andreja Smolčić
Subject: FW: External study on the availability of medicinal products for human use

Dear colleagues,

Thank you very much for sharing with us the objective, methodology, conclusions and recommendations of the study on availability of medicinal products for human use. Since Croatia hasn't been the EU Member State at the time the study was conducted, we didn't take a part but we are very interested in the topic of the availability of medicinal products with a focus on the smaller EU Member States. Although we have about 4000 authorised medicinal products (this number includes MP with the same name and active substance but with different strengths), we have recently faced some availability issues regarding the centrally authorised medicinal products (CP) which are not marketed in Croatia.

Since the scope of the study was to assess the impact of pharmaceutical legislation in terms of availability, we've made an overview of provisions in the EU legislation we've implemented in our national legislation and that we consider to have a positive impact on supply of medicinal products on the territory of the Republic of Croatia:

1. There is in place the obligation for marketing authorisation holders to notify the Agency in writing:

a) about the date of first actual market placement of the medicinal product (not later than within 15 days),
b) should he decide to discontinue marketing of a medicinal product or to withdraw it from the market, either temporarily or permanently, before the expiry of its marketing authorisation or should he decide to apply for the revocation of the marketing authorisation or not to apply for the authorisation renewal, at least two months before the interruption in the placing on the market of the product (except in case of an urgent withdrawal procedure or other exceptional circumstances),
c) in case of circumstances which could result in a disturbed supply of a medicinal product or its shortage on the Croatian market.

The data regarding the temporary or permanently interruptions in supply chain and shortages are public and available on our web page.

2. For medicinal products that are not intended to be directly used by the user or the patient, or in case of problems in the market supply of the medicinal product, and in accordance with the measures necessary for preserving human health, we have a stipulation in our Medicinal Product Act that the Agency may approve exemption from the requirement that the label and the leaflet must be in the Croatian language, provided that the text is in Latin script, pursuant to a written reasoned application submitted by the authorisation holder - "translation exemptions"-very often used provision
3. The Agency may exceptionally allow the entry or importation of medicinal products which are not authorised in the Republic of Croatia, if there is a medically justified need to protect human health, in case of natural disasters or other emergencies or for emergency treatments of individual patients with a medicinal product prescribed

by a medical doctor or dental medicine doctor in charge (Article 5. Directive 2001/83/EC) – importing licenses (unauthorised medicinal products)- the tool we use the most

4. The marketing authorisation holder, as well as any natural or legal person engaged in distribution of the concerned medicinal product on the territory of the Republic of Croatia, shall ensure, within the limits of their responsibilities, a suitable and continuous supply of medicinal products (!!! Public service obligation (Article 81 Directive 2001/83/EC) which represents one of the conditions for wholesalers to maintain their WH license) – we haven't experienced the shortages due to parallel export yet but we have to mention that we have very low prices of medicinal products due to reimbursement negotiations (price referencing) and we are expecting to have huge supply issues in the future (like the Italy example mentioned in the study)
5. For the purpose of human health protection, the Ministry or the Agency may in justified cases decide that the Agency shall, ex officio, grant the marketing authorisation to a medicinal product which neither has an authorisation nor was the authorisation applied for in the Republic of Croatia, but which has been authorised in another EU Member State ("Cyprus clause") – **the stipulation we've never used**
6. The Agency shall cancel any marketing authorisation for a medicinal product which within three years of its granting is not followed by the actual placing on the market of the Republic of Croatia ("Sunset clause", this stipulation has become effective from 1st of July 2013. so the earliest date when a marketing authorisation can cease to be valid under the "sunset clause" is 1st July 2016.)

With regards to the conclusions of the study we consider the main availability problem for us the fact that some of the CP products will never be marketed in Croatia as a small market country and we, as the competent authority for monitoring and taking appropriate measures to ensure the regular supply of medicinal products on the territory of the Republic of Croatia, don't have an adequate tool to solve this problem.

If you have any other questions or need an additional clarification regarding the tools used to ensure the availability of medicinal products for human use in Croatia, please don't hesitate to contact us again.

Kind regards,

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