

Number: 01-0120/2009-1

Date: March 12, 2009

**To all Marketing Authorisation Holders****SUBJECT: Cessation of the marketing authorisation if the medicinal product is not marketed**

Dear Sir or Madam,

According to Article 45(1) of Medicinal Products Act (Official Gazette of the RS, No. 31/06 and 45/08, hereafter Act) any marketing authorisation which within three consecutive years of its granting is not followed by the actual placing on the market of the authorised product, shall cease to be valid. Notwithstanding this provision, the competent authority for medicinal products shall be entitled not to withdraw marketing authorisation in exceptional well-justified cases and for the needs of protecting public health.

Since the provision came into effect on April 8, 2006, all marketing authorisation holders are asked to send the list of medicinal products subject to the first paragraph of article 45 of the Act to Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (hereafter JAZMP), no later than April 7, 2009.

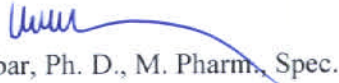
The marketing authorisation remains valid if at least one presentation of the marketing authorisation is available at the wholesale marketing authorisation holder or a medicinal product wholesale trader. For the purpose of this provision the global marketing authorisation is taken into account, which means that all marketing authorisations which are a result of an extensions and variations of an initial marketing authorisation (e.g. new therapeutic indication, new strength, new pharmaceutical form, etc.) are treated as a part of the same marketing authorisation.

The additional explanations regarding this provision are available in 'Notice to Applicants', Chapter 1, Section 2.4.2., published by the European Commission on the following web page:  
[http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/a/vol2a\\_chap1\\_2005-11-pdf](http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/a/vol2a_chap1_2005-11-pdf).

We would like to point out the second paragraph of the Article 45 of the Act, which provides that the competent authority responsible for medicinal products in exceptional duly justified cases and for the purpose of protection of public health, may grant exemptions.

If Article 45(2) of the Act is referred and if the exceptional circumstances are well justified, the application, including the list of medicinal products in an addendum shall be submitted to JAZMP – Pharmaceutical inspection sector. JAZMP will decide on the eligibility of your statements and conclude the procedure.

Yours sincerely,

  
Martina Cvelbar, Ph. D., M. Pharm., Spec.  
Director