

Number: 01-032/10-1  
Date: 29 January 2010

**Subject: Notice to persons liable for the payment of the  
annual fees for 2010**

Dear Sir/Madam,

In reply to inquiries regarding the payment of the annual fees resulting from Article 94 of the Medicinal Products Act (Official Gazette of the Republic of Slovenia, no. 31/06 - hereinafter: ZZdr-1) and Article 3 of the Rules on the charges and expenses of procedures in the field of medicines and medical devices (Official Gazette of the Republic of Slovenia, no. 3/07), we are forwarding you the following replies:

- The annual fees shall be paid for each pharmaceutical form of a medicinal product regardless of the strength or packaging of individual pharmaceutical forms.
- The annual fees shall be paid for medicinal products which have a marketing authorisation regardless of whether they were actually present on the market in the current year or not. A medicinal product shall be placed on the market from the day of issue of the marketing authorisation, or it shall be placed on the market within a period of three years following the issue of the marketing authorisation. Otherwise the marketing authorisation shall be revoked.
- The annual fees shall be paid for the medicinal product which possesses a marketing authorisation regardless of whether the marketing authorisation expired in the current year.
- The marketing authorisation holder for a medicinal product which obtained a marketing authorisation according to the centralised procedure is not obliged to pay the annual fees to the authority competent for medicinal products in the Republic of Slovenia.
- The annual fees shall not be paid for medicinal products which do not possess a marketing authorisation.
- The annual fees for medicinal products which will obtain a marketing authorisation after 28 February 2010 shall be paid in the following year (by 28 February 2011).
- If you are a representative for a number of marketing authorisation holders for medicinal products, the annual fees for medicinal products shall be paid for each marketing authorisation holder separately.
- Please forward evidence on the payment of the fees with an accompanying cover letter by mail to the following address: Javna agencija RS za zdravila in medicinske pripomočke (JAZMP), Služba za finance, računovodstvo in javna naročila, Ptujška ulica 21, 1000 Ljubljana. If you intend to implement total payment for all medicinal products, please also include a precise specification of payment in the accompanying letter.
- Payment manner:
  - ◆ Payers with their head office in Slovenia: to the JAZMP sub-account no. 01100-6000020296 with one of the following references:
    - 00 760002-402 (for medicinal products for human use)
    - 00 760002-403 (for veterinary medicinal products)
    - 00 760002-404 (permit for the manufacture, wholesale or retail of medicinal products)

- ◆ Payers with their head office outside of Slovenia: JAZMP Account no.: 01100-6000020296; bank: Bank of Slovenia, Slovenska 35, 1505 Ljubljana; IBAN: SI56011006000020296; SWIFT code: BSLJSI2X; Ref. no:  
00 760102-402 (for medicinal products for human use)  
00 760102-403 (for veterinary medicinal products)  
00 760102-404 (for a single manufacturing authorisation, single wholesaler authorisation, or single retail store authorisation).

Thank you for your cooperation and best regards

dr.Martina Cvelbar, mag.farm.,spec.  
direktorica

