

Date: 27.01.2014

Notification to persons liable for payment of annual fees in 2014

In light of the payment of annual fees referred to in Article 94 of the Medicinal Products Act (Uradni list RS (Official Gazette of the Republic of Slovenia), Nos. 31/06 and 45/08 - ZZdr-1), Article 62 of the Medical Devices Act (Uradni list RS, No. 98/09 - ZMedPri), Article 4 of the Rules on fees in the area of medicines (Uradni list. RS, No. 65/11) and Article 4 of the Rules relating to fees in the field of medical devices (Uradni list RS, No. 37/10),

we **inform all persons liable** for the payment of annual fees that **payment notices** for the payment of annual fees for 2014 must be received by no later than **28 February 2014**. A list of all the authorisations acquired up to 31 December 2013 shall form an integral part of the payment notice. The payment notice by which the persons liable for the payment of annual fees will be called upon will contain the amount and the method of payment of fees.

- Payment notices will be received by:
 - the holders of the marketing authorisations for a medicinal product or the parallel import licence for a medicinal product;
 - the holders of the marketing authorisations for a homeopathic medicinal product;
 - the holders of medicinal product manufacturing authorisations;
 - the holders of wholesale distribution authorisations for medicinal products;
 - the holders of retail sale authorisations for medicinal products in specialised shops; and
 - notified bodies for the conformity assessment procedure.

- Particularities in respect of annual fees for medicinal products:
 - An annual fee shall be paid for every **pharmaceutical form** of medicinal product, **irrespective** of the strength or packaging of the individual pharmaceutical form.
 - An annual fee shall be paid for medicinal products that have marketing authorisation, irrespective of the fact whether they are present in the market or not in the current year.
 - An annual fee shall be paid for medicinal products that have a marketing authorisation applicable as of 31 December 2013, irrespective of whether or not the marketing authorisation will expire in 2014.
 - An annual fee shall not be charged for medicinal products that have obtained a marketing authorisation via the centralised procedure;
 - An annual fee shall not be paid for medicinal products that have no marketing authorisation;
 - An annual fee shall be paid for medicinal products whose marketing authorisation has expired and is in the process of being renewed.

- Representatives for several holders of marketing authorisations for medicinal products shall receive payment notices to pay annual fees for each holder separately.

- Persons liable for payment shall send claims concerning payment notices to the following address: Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP), Sektor za finance in računovodstvo, Ptujška ulica 21, 1000 Ljubljana or by email to: Fees@jazmp.si.

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