



**Re: Payment of annual fees 2012 for Marketing Authorisations (AIC) valid at the date of May 23<sup>rd</sup>, 2012**

Dear Company,

Through Resolution no. 21 of May 30, 2012, the Board of Directors of AIFA implemented Art. 4, paragraph 5 of the Decree of the Ministry of Health dated March 29, 2012, n. 53, adopted pursuant to art. 17, paragraph 10 of the Decree Law of 6 July 2011, n. 98, converted into Law no. 111 of July 15, 2011, under which an annual fee of EUR 1,000.00 (thousand/00) payable by each holder has been introduced for each valid marketing authorization (AIC, in Italian).

<http://www.agenziafarmaco.gov.it/it/content/informazioni-sul-sistema-di-versamento-tariffe>

Under the abovementioned Resolution, in particular, it has been established that "each holder of a marketing authorization is required to pay to AIFA an annual fee of euro 1,000.00 for each marketing authorization resulting valid as of December 31st of the previous year. The payment has to be performed through the online payment system on the website of AIFA, no later than the end of July.

Upon first application, the annual fee is due for each marketing authorization valid at the date of entry into force of the Decree of the Ministry of Health March 29, 2012, n. 53, except for the case where the holder, by that date, has applied for withdrawal of the said marketing authorizations."

Please note that fees are not due for valid marketing authorizations released following a centralized procedure.

## **1. FULL PAYMENT**

In order to fulfill the obligations set out under Resolution no. 21 of May 30, 2012 and art. 17, paragraph 10 of the Decree Law 6 July 2011, n. 98, a pre-filled MAV Bulletin will be delivered, showing the total amount due, calculated by multiplying Euro 1.000,00 (thousand/00) for the number of valid marketing authorizations of which, according to the information contained in the

AIFA database, the company appears to be the holder at the date of entry into force of the Decree of the Ministry of Health March 29, 2012, n. 53 (May 23, 2012). The MAV is payable at any bank with no commission.

A complete list of all valid AIC for each company (code SIS), is available in the section "System of payment of the fees" on the AIFA website. (<http://www.agenziafarmaco.gov.it/it/content/informazioni-sul-sistema-di-versamento-tariffe>)

### **1. bis FULL PAYMENT VIA BANK TRANSFER**

Should a company face any difficulties (eg. foreign companies) in performing the payment of the fees by MAV, the payment of the same amount indicated in the MAV may be made by bank transfer to the account of AIFA, IBAN: IT 76 V 05424 04 297 000 000 000 395; Swift code: BPBAIT3B.

In the "REASON FOR PAYMENT" section it is mandatory to indicate the full name of the company performing the payment and the words "2012 annual fees - full payment".

### **2. REDUCED PAYMENT FOR MICRO, SMALL AND MEDIUM SIZED COMPANIES**

Pursuant to art. 4, paragraph 6 of the Decree of the Ministry of Health March 29, 2012, n. 53 and paragraph 3 of resolution no. 21 of 30 May 2012, the annual fee due for each AIC is reduced to euro 750.00 if the holder of the authorization is a micro, small or medium sized company, as defined in Recommendation 2003/361/EEC.

A similar reduction in the amount of the annual fees applies if the holder of the AIC is a public company. Therefore, if the company is a micro, small or medium sized enterprise or a public company, the amount due shall be calculated by multiplying Euro 750.00 for the number of valid marketing authorizations held by that company as of May 23<sup>rd</sup>, 2012.

For the payment of this amount, the company should not use the MAV and will proceed by bank transfer to the account of AIFA, IBAN: IT 76 V 05424 04 297 000 000 000 395; Swift.: BPBAIT3B.

In the "REASON FOR PAYMENT" it is mandatory to indicate the full name of the company making the payment and the following wording "2012 annual fees - reduced payment".

In order to make the reduced payment, the company must necessarily provide the documentation or make appropriate self-certification to possess the requirements provided for in Article 2 of Recommendation 2003/361/CEE, in accordance with articles 46 and 47 of DPR 445/2000.

Such documentation or self-certification as per attached form, must be submitted by July 31<sup>st</sup>, 2012 and no later than 15 days after receipt of the precompiled MAV Bulletin to: "Agenzia Italiana

del Farmaco, Ufficio Affari Amministrativi, Contabilità e Bilancio, Via del Tritone n. 181, (00187) Rome" or to the following address by certified mail: s.capponi@aifa.mailcert.it.

AIFA reserves the right to make any appropriate checks to assess the actual possession by the company of the requirements set out in Article. 2 of Recommendation 2003/361/CEE.

### **3. PAYMENT OF A DIFFERENT AMOUNT**

Should the amounts indicated in the MAV be deemed incorrect, the company is nonetheless required to perform the payment of the amount it deems appropriate within the deadline specified in paragraph 4) of the present notice, without prejudice to subsequent checks performed by AIFA.

For the payment of such amount, the company will proceed by bank transfer to the account of AIFA, IBAN: IT 76 V 05424 04 297 000 000 000 395; Swift code: BPBAIT3B.

In the "REASON FOR PAYMENT" it is mandatory to indicate the full name of the company making the payment and the following wording "2012 annual fees – payment of a different amount".

In order to make the payment of a different amount, the company shall provide a declaration pursuant to articles 46 and 47 of DPR 445/2000 containing an indication of the AICs for which it deems to have or not to have to perform the payment.

Such self-certification, as per attached form, must be submitted by July 31<sup>st</sup>, 2012 and no later than 15 days after receipt of a precompiled MAV Bulletin to: "Agenzia Italiana del Farmaco, Ufficio Affari Amministrativi, Contabilità e Bilancio, Via del Tritone n. 181, (00187) Roma" or to the following address by certified mail: s.capponi@aifa.mailcert.it.

AIFA reserves the right to make any appropriate checks aimed at verifying the actual ownership by the company of the marketing authorizations for which payment is made.

Please note that the amount of the fees due shall be calculated using the formula: "euro 1000,00 x number of AICs held by the company as of May 23<sup>rd</sup>, 2012".

In the case of micro / small and medium sized companies / public companies the amount of the annual fees due shall be calculated using the following formula: "Euro 750.00 x number of AICs held by the Company as of May 23<sup>rd</sup>, 2012". In this case, in addition to the certification concerning the marketing authorizations for which payment is made, there is no prejudice to the obligations of transmission to AIFA set out in paragraph 2 above.

### **4. DEADLINE FOR THE PAYMENTS AND SANCTIONS**

The payment of the annual fees by bank transfer or MAV, has to be made by July, 31<sup>st</sup>, 2012 and in any case no later than 15 days after receipt of the precompiled MAV Bulletin. AIFA will verify the

correctness of the payments of the annual fees performed by the company and, in the case of non-payment of sums due, it will start procedures for the recovery of such amounts, suspending the online management of the marketing authorizations for which the payment has not been performed.

For further information, please contact Mrs. Alessandra Antonini, Mon./Fri. (tel. 0039.06.59784603, email address: [supportoamministrativo-POL@aifa.gov.it](mailto:supportoamministrativo-POL@aifa.gov.it)). To receive the precompiled MAV form via email, please write to the following email address: [comp.esecutivocassa@popolarebari.it](mailto:comp.esecutivocassa@popolarebari.it).