

**ACCOUNTING AND BALANCE OFFICE****Subject: Payment of 2024 annual fees for Marketing Authorisations (MAs) valid as of 31 December 2023**

Dear Company,

through the Resolution no. 21 of May 30, 2012, the Board of Directors of the Italian Medicines Agency (hereinafter "AIFA") implemented the article 4, paragraph 5 of the Decree of the Ministry of Health dated March 29, 2012, n. 53, adopted pursuant to article 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 payable by each holder has been introduced for each valid Marketing Authorisation ("AIC" in Italian) (<https://www.aifa.gov.it/tariffe>).

Under the above mentioned Resolution no. 21 of May 30, 2012, it has been particularly established that *"each marketing authorisation holder is required to correspond to AIFA, through the online payment system on the AIFA website, no later than the end of July, an annual fee for each marketing authorisation resulting valid until December 31st of the previous year."*

With reference to homeopathic medicinal products and to herbal medicinal products based on traditional use, the decree of the Minister of Health of 6 December 2012, repealing the decree of the Minister of Health of 21 December 2012, stipulates in Article 2 that the annual fee payable to AIFA by each marketing authorisation holder amounts to 20% of the fee laid down in Article 4, paragraph 5 of the Decree of the Minister of Health no. 53 of 29 March 2012.

Following the tariff increase set out in Article 3 of the Decree of the Minister of Health of 6 December 2016, the fee due for 2024 amounts to:

- euro 366,55 (three hundred sixty-six/55) for homeopathic medicinal products and for herbal medicinal products based on traditional use;
- euro 1.832,77 (one thousand eight hundred thirty-two/77) for any other medicinal product.

Please note that the fee is not due for valid MAs granted through centralised procedures.

The full list of the valid MAs, divided by single companies (SIS code), is available on AIFA institutional website in the section "Payment of fees and annual duties". (<https://www.aifa.gov.it/tariffe>)

1. FULL PAYMENT

In order to fulfill the obligations set out under the Resolution no. 21 of May 30, 2012 and article 17, paragraph 10 of the Decree Law 6 July 2011, n. 98, it is possible to use the AIFA online system "Pagamenti online – POL" by following the link "Annual Fee" <https://servizionline.aifa.gov.it>

The platform, upon recognition of the user as a delegate to pay on behalf of the Company (SIS code), automatically determines the total amount due, which is calculated by multiplying the amount due for the single authorisation by the MA number (valid pursuant to the findings of the Agency's database) held by the Company as of 31 December 2023.

As highlighted on the relevant web page, the payment can only be made in the following ways:

- ❑ through **the PagoPA system**, which allows to pay by credit card or CBILL directly within the application;
- ❑ for companies based abroad and/or in exceptional cases also through **bank transfer** to AIFA's account — IBAN IT26-F-05034-03200-000000010449. It is mandatory to report in the field "REASON FOR PAYMENT" the POL code for which the payment notice must be generated.

2. REDUCED PAYMENT FOR MICRO, SMALL AND MEDIUM ENTERPRISES AND FOR PUBLIC COMPANIES

Pursuant to Article 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 and to Article 6, paragraph 2 of the Decree of the Minister of Health of 6 December 2016, the annual fee due for each MA is reduced by 25% in the following cases:

- the MA holder is a micro, small or medium enterprise, as defined by Recommendation 2003/361/EC;
- The MA holder is a public company.

The reduced amount due for 2024 is equal to:

- **euro 274,91 (two hundred seventy-four/91) for homeopathic medicinal products and for herbal medicinal products based on traditional use;**
- **euro 1.374,57 (one thousand three hundred seventy-four/57) for any other medicinal product.**

In order to pay the reduced amount, the Company shall show compliance with the requirements by providing appropriate documentation or by issuing a self-certification pursuant to Article 46 and 47 of the Decree no. 445 of the President of the Republic of 28 December 2000 using the forms available at the following link: : <https://www.aifa.gov.it/tariffe>. To be eligible for the abovementioned benefits for the current year, such documentation or self-certification shall be submitted by referring to data/information as of 31 December of the previous year (e.g. to be eligible for the benefits in 2024, data/information shall refer as of 31 December 2023) and, provided the conditions still exist, it shall be submitted again for the following year, under penalty of forfeiture of the benefit.

Such documentation or self-certification shall be sent to the certified email address protocollo@pec.aifa.gov.it. The Italian Medicines Agency reserves the right to make any appropriate control to verify that the Company actually possesses the self-certified requirements.

As highlighted on the relevant web page, the payment can only be made in the following ways:

- ❑ through the **PagoPA system**, which allows to pay by credit card or CBILL directly within the application;
- ❑ for companies based abroad and/or in exceptional cases also through **bank transfer** to AIFA's account — IBAN IT26-F-05034-03200-000000010449. It is mandatory to report in the field "REASON FOR PAYMENT" the POL code for which the payment notice must be generated.

3. PAYMENT OF A DIFFERENT AMOUNT

Should the amounts indicated 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.

As highlighted on the relevant web page, the payment can only be made in the following ways:

- ❑ through the **PagoPA system**, which allows to pay by credit card or CBILL directly within the application;
- ❑ for companies based abroad and/or in exceptional cases also through **bank transfer** to AIFA's account — IBAN IT26-F-05034-03200-000000010449. It is mandatory to report in the field "REASON FOR PAYMENT" the POL code for which the payment notice must be generated.

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

MAs for which it is required to perform the payment or not. Such self-certification, as per the attached form, shall be submitted by 30 September 2024 via Certified Mail (PEC) to the mailbox protocollo@pec.aifa.gov.it specifying in the subject of the e-mail “different payments form”. AIFA reserves the right to verify the Company's ownership of the marketing authorisations for which the payment is made.

Please note that the amount due shall be calculated according to the following formula:

- euro 366,55 (three hundred sixty-six/55) multiplied by the number of MAs that the Company holds as of 31 December 2023, related to homeopathic medicinal products and herbal medicinal products based on traditional use;
- euro 1.832,77 (one thousand eight hundred thirty-two/77) multiplied by the number of MAs held by the Company as of 31 December 2023, relating to any other medicinal product.

For micro/small enterprises and public companies, the amount of the annual fee due shall be calculated through the following formula:

- euro 274,91 (two hundred seventy-four/91) multiplied by the number of MAs related to homeopathic medicinal products and herbal medicinal products based on traditional use, that the Company holds as of 31 December 2023;
- euro 1.374,57 (one thousand three hundred seventy-four/57) multiplied by the number of MAs held by the Company as of 31 December 2023 which relate to any other medicinal product.

In such case, the MAs for which the payment was made are certified, without prejudice to the obligations of transmission to AIFA referred to in point 2.

4. DEADLINE FOR THE PAYMENTS AND SANCTIONS

The payment of the annual fees must be made by 31 July 2024 and in any case no later than 15 days from the effective availability of the payment service on the online platform.

AIFA will verify whether the payments of the annual fees performed by the companies are regular and, in the case of any irregularity, it will proceed to debt collection procedures, and will suspend the online management of the marketing authorisations for which the payment has not been performed.

Please note that, according to the provisions of the AIFA DG Decision no. 118/2023, for the recovery of credits due from debtors of the annual fee charged to each Marketing Authorization Holder, pursuant to art. 17, paragraph 10, letter d) of decree-law no. 98 of 6 July 2011, converted into law no. 111 of 15 July 2011 and to art. 4, paragraph 5, of the decree of the Minister of Health no. 53 of 29 March 2012, AIFA makes use of the credit recovery system by means of a notice of assessment and, in the event of non-payment within the terms prescribed therein, subsequent compulsory collection.

For further information, please send an e-mail to the following address c.silvagni@aifa.gov.it (operating from Monday to Friday).

Best regards

Rome, 01/07/2024

Head of the Accounting and Balance Office
(Dott. Guglielmo Di Balsamo)