

**ACCOUNTING AND BALANCE OFFICE****Subject: Payment of 2020 annual fees for Marketing Authorizations (AIC) valid as of December 31st 2019**

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 authorization (hereinafter "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 authorization 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 authorization resulting valid until December 31<sup>st</sup> 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 2020 amounts to:**

- **euro 315,39 (three hundred fifteen/39) for homeopathic medicinal products and for herbal medicinal products based on traditional use;**
- **euro 1.576,95 (one thousand five hundred seventy-six/95) 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 “Versamento tariffe e diritti annuali”. (<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 2018.

As underlined on the website of the on line payment system, the balance due may be paid only as follows:

- ❑ accessing the PagoPA on line system which allows direct payments via credit cards
- ❑ by bank transfer to AIFA's account - IBAN IT26-F-05034-03200-000000010449: please note that in the "REASON FOR PAYMENT" section it is mandatory to indicate the POL code; once the bank transfer is submitted, the user is also required to log in the system again in order to provide the CRO/TRN/SEPA code (composed of a maximum of 35 characters) and the date of the bank transfer (see paragraph 2.6.3 of the manual published on the page "Service Guide", which can be reached following authentication to the POL system) as a self-certification of the payment.

## 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 2020 is equal to:**

- **euro 236,54 (two hundred thirty-six/54) for homeopathic medicinal products and for herbal medicinal products based on traditional use;**
- **euro 1.182,71 (one thousand one hundred eighty-two/71) 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 2020, data/information shall refer as of 31 December 2019) 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](mailto: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 underlined on the website, the balance due may be paid only as follows:

- ❑ by accessing the PagoPA on line system which allows direct payments via credit cards
- ❑ by bank transfer to AIFA's account - IBAN IT26-F-05034-03200-000000010449: please note that in the "REASON FOR PAYMENT" section it is mandatory to indicate the POL code; once the bank transfer is submitted, the user is also required to log in the system again in order to provide the CRO/TRN/SEPA code (composed of a maximum of 35 characters) and the date of the bank transfer (see paragraph 2.6.3 of the manual published on the page "Service Guide", which can be reached following authentication to the POL system) as a self-certification of the payment.

### **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 underlined on the website, the balance due may be paid only as follows:

- ❑ by accessing the PagoPA on line system which allows direct payments via credit cards
- ❑ by bank transfer to AIFA's account - IBAN IT26-F-05034-03200-000000010449: please note that in the "REASON FOR PAYMENT" section it is mandatory to indicate the POL code; once the bank transfer is submitted, the user is also required to log in the system again in order to provide the CRO/TRN/SEPA code (composed of a maximum of 35 characters) and the date of the bank transfer (see paragraph 2.6.3 of the manual published on the page "Service Guide", which can be reached following authentication to the POL system) as a self-certification of the payment.

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 is required to perform the payment or not. Such self-certification, as per the

attached form, shall be submitted by 30<sup>th</sup> September 2020 via Certified Mail (PEC) to the mailbox [protocollo@pec.aifa.gov.it](mailto: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 authorizations for which the payment is made.

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

- euro 315,39 (three hundred fifteen/39) multiplied by the number of MAs that the Company holds as of 31 December 2019, related to homeopathic medicinal products and herbal medicinal products based on traditional use;
- euro 1.576,95 (one thousand five hundred seventy-six/95) multiplied by the number of MAs held by the Company as of 31 December 2019, 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 236,54 (two hundred thirty-six/54) 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 2019;
- euro 1.182,71 (one thousand one hundred eighty-two/71) multiplied by the number of MAs held by the Company as of 31 December 2019 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 July, 31<sup>st</sup> 2020 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 authorizations for which the payment has not been performed.

For further information, please send an e-mail to the following addresses [c.silvagni@aifa.gov.it](mailto:c.silvagni@aifa.gov.it) and [v.maldonado.ext@aifa.gov.it](mailto:v.maldonado.ext@aifa.gov.it) (operating from Monday to Friday).

Best regards

Rome, 07/07/2020

**Head of the Accounting and Balance Office**  
*(Stefania Cuccagna)*