ANNUAL FEE

PUBLIC NOTICE TO PHARMACEUTICAL COMPANIES

Frequently asked questions (FAQs) concerning payment of the annual fee referred to in Article 17, paragraph 10, of Decree-law 6 July 2011, no. 98, converted into Law no. 111 of 15 July 2011, to Article 4, paragraph 5 of the Decree of the Minister of Health of 29 March 2012, no. 53 and to Resolution no. 21 of AIFA's Board of Directors of 30 May 2012

Dear Companies,

Please be informed that AIFA's Board of Directors, with resolution no. 21 of 30 May 2012, implemented Article 4, paragraph 5, of the Decree of the Minister of Health of 29 March 2012, no. 53, issued pursuant to article 17, paragraph 10, of the Decree-law of 6 July 2011, no. 98, converted into Law no. 111, whereby, for each valid marketing authorization (MA), an annual fee has been introduced for each MA holder.

In particular, with the aforementioned resolution of 30 May 2012, no. 21, it was established that *"each marketing authorization holder is required to pay to the Italian Medicines Agency, through the online payment system on its institutional website, by and no later than July, an annual fee for each marketing authorization (6 digit MA) valid as of 31 December of the previous year"*.

Considering the many requests for clarification received by the Agency on the methods of payment of the annual fee, AIFA has decided to publish this public notice, with FAQs providing practical information for the correct payment of the fee.

1. In the event of voluntary withdrawal of the MA, from when does it apply for the purposes of paying the annual fee?

The validity of the voluntary withdrawal applies from the day following the publication of AIFA's provision in the Official Gazette.

It is not possible to refer to the submission date of the withdrawal request by the company for the effective date of the voluntary withdrawal. Moreover, in the specific case of waiver of the MA by the holding company, AIFA, before granting the voluntary withdrawal, is required to verify that this is without prejudice to public health reasons, pursuant to Article 38, paragraph 9, of Legislative decree 24 April 2006, no. 219.

The same can apply by analogy to holders of parallel import authorisation.

2. If AIFA issues a revocation before 31 December but this is published in the Official Gazette in January of the following year, is the company required to pay the annual fee referring to the previous year?

In order to avoid discriminatory behaviours towards pharmaceutical companies due to the different term of validity of the revocation measures, the annual fee shall be paid in any case.

In fact, it is generally accepted that the term of validity of the aforementioned provisions runs from the day following the publication date of AIFA's provision in the Official Gazette.

3. If a MA expires due to the "Sunset Clause", i.e. due to non-marketing of the medicine, from when is the MA considered to be expired?

Pursuant to Article 38, paragraph 5, of Legislative Decree no. 219/2006, the MA of a medicine expires if it is not marketed in the national territory within three years following the issuing date. According to paragraph 7 of the same Article, the MA is also withdrawn if none of the packages authorised under the same MA of a medicine, regularly marketed, is actually placed on the Italian market for three consecutive years.

AIFA publishes in the Official Gazette the data relating to the expired MAs. AIFA's provision purely serves as acknowledgement, considering that expiry occurs by law.

AIFA publishes the list of MAs about to expire at least two months in advance of the alleged expiry date, through the bimonthly publication "Warning of upcoming expiry" on its institutional website.

Therefore, the MA of the medicine expires as of the date indicated in the document "Warning of upcoming expiry", published on AIFA's institutional website.

In fact, the AIFA resolutions published in the Official Gazette state: *"The medicines in the list attached to this resolution expired as of the date indicated for each of them [...]".*

The pharmaceutical company is in any case required to pay the entire amount of the annual fee relating to the year preceding the MA cancellation, as no periodic splitting is envisaged for paying the annual fee.

For instance, if the MA expires on 1 August 2017, the company is required to pay the **2017 annual fee** (for the MAs valid as of 31/12/2016) but **not the 2018 annual fee** (for the MAs valid as of 31/12/2017).

Please note that if a waiver application is accepted, the annual fee is still due until the effective expiry of the MA.

4. Are companies holding MAs of suspended medicines due to pay the annual fee?

The suspension, being provisional by definition and not producing definitive effects on the MA, cannot affect the payment of the annual fee. Therefore, companies shall continue to pay the annual fee even if their MAs are suspended.

5. Are the holders of the parallel import authorisation (parallel product authorisation, PPA) and parallel distributors whose drug of origin has been authorised with a centralised procedure required to pay the annual fee?

The PPA holders are required to pay the annual fee. Please note that the Council of State highlighted that Article 17, paragraph 10, of Legislative Decree n. 98/2011, introduced a provision aimed at guaranteeing the maximum functionality of AIFA as for the relevance and increased complexity of its competences; the provision also aimed at strengthening the management of the strategic areas corresponding to the guidelines established by the Ministry of Health and so on (Council of State, judgement no. 1285/2015).

Instead, in the case of parallel distribution, since the medicines are issued through a centralised procedure, the annual fee shall not be paid.

6. If the MA/PPA code owned by the company as of 31 December of the previous year has not yet been placed on the Italian market for patent reasons or is still under reclassification (Class C non-negotiated (nn)), shall the company still pay the annual fee?

Yes; paragraph 10, letter d) of Article 17 of the Decree-law 6 July 2011 no. 98, converted with amendments by Art. 1, paragraph 1, Law 15 July 2011, no. 111, provides for "the introduction of an annual fee to be paid by each marketing authorisation holder for the operation, updating and implementation of the IT functions of the database of authorised or registered medicines for marketing purposes, as well as for the IT management of the related authorisation procedures".

The resolution of AIFA's Board of Directors no. 21 of 30 May 2012 also states that each MAH is required to pay to the Italian Medicines Agency, no later than July, an annual fee for each MA valid as of 31 December of the previous year.

Therefore, the legislation does not provide for waivers relating to medicines not yet marketed, for which no applications have been submitted to AIFA or which have not yet been assessed for reimbursement purposes.