

IMPORTANT NOTICE TO ALL PHARMACEUTICAL COMPANIES

DECREE DECEMBER 21st 2012

Update of the amounts of fees and charges due

for services rendered at the request of stakeholders

Published in the Official Journal of the Italian Republic n. 63 of March 15th 2013

We hereby inform all pharmaceutical companies that the Decree of the Minister of Health dated December 21st 2012 will enter into force on March 30th 2013.

By means of this Decree, the fees applied at the date of entry into force of the law converting the *decreto legge* of September 13th 2012 n. 158 (see Annex 1 to the Decree) are updated with 10% increase in the amounts.

The Decree also identifies the amounts due for services not yet priced out (see Annex 2 to Decree), in a manner that takes into due account the similarities between the different services rendered and fixes, for each marketing authorization, the annual fees to be paid for the registration of each homeopathic and herbal medicinal product for traditional use. Such annual fees are fixed at 20% of the amount due under Art. 4 paragraph 5 of D.M. March 29, 2012 n. 53.

Entry into force

Article 7 provides for the entry into force of the Decree on the fifteenth day following its publication in the Official Journal of March 15th 2013.

From March 30th 2013, therefore, it will be possible to pay the new amounts and articles 4 and 5, governing payment of fees, submission of applications, reimbursement of fees and reuse at the request of the company will be fully into force.

In particular, for all payments performed before the entry into force of the new tariffs, companies are required to submit to AIFA, no later than May 29th, 2013, all applications for required services together with evidence of the payment of the said fees.

Pursuant to art. 4, second paragraph, in fact, if applications for services are not received within sixty days from the payment, the amounts paid will be reimbursed in accordance with Article 5 and a 10% deduction, up to a maximum of € 500.00 for each application for reimbursement shall apply.

POL platform – AIFA payment system

Platform will be closed for maintenance from March 30th to April 5th 2013 in order to update the fees in the section “*online payment*” of the Aifa official website.

In case of emergency, it will be possible to perform payments on the usual accounts of AIFA or at the Ministry of Health, attaching receipts thereof to the application. A new Pol will subsequently have to be created, with a rate corresponding to the required service and evidence of the performed payments.

Reimbursement of fees and reuse upon request of pharmaceutical companies

Art. 5 of the Decree identifies the following situations in which it is possible to apply for a reimbursement of fees:

- WAIVER, intervening before the scientific and technical evaluation of the process;
- FAILURE IN SUBMITTING the application within 60 days from the payment of the fees;
- INCORRECT PAYMENT

In all cases where a reimbursement is foreseen, the Italian Medicines Agency, upon request of the interested party, may allocate that amount for the payment of additional and/or subsequent services.

In any case, pursuant to paragraph 2 of Article 5, the Italian Medicines Agency shall retain an amount equal to 10% of the sum paid to cover the costs for administrative activities, up to a maximum of € 500.00 for each request of reimbursement.

New guidelines concerning applications for reimbursement submitted by the companies before the entry into force of this Decree will soon be adopted.

Rome, March 28th 2013

The Manager

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