

Supplementary notice to notices dated 26 March 2020 and 24 April 2020 - Methods for stamp duty payment pursuant to Italian Presidential Decree no. 642/72 by foreign entities

Further to notice dated 26 March 2020, “Electronically-submitted applications to the Italian Medicines Agency: methods for stamp duty payment” (available at the following link <https://www.aifa.gov.it/-/istanze-presentate-all-agenzia-italiana-del-farmaco-per-via-telematica-modalita-di-assolvimento-dell-imposta-di-bollo>), and notice dated 24 April 2020, “Electronic service of authorisation documents issued by the Medicinal Products Authorisation Department and the HTA and Pharmaceutical Economics Division” (available at the following link [https://www.aifa.gov.it/documents/20142/1150130/com-Notifica atti EN 24.04.2020.pdf](https://www.aifa.gov.it/documents/20142/1150130/com-Notifica+atti+EN+24.04.2020.pdf)), the Italian Medicines Agency (AIFA) hereby clarifies the following:

In light of the difficulties encountered by foreign entities when paying the stamp duty as referred to in Italian Presidential Decree no. 642/72 by means of the procedures indicated in the above-mentioned notices, and having regard to the current situation, AIFA will accept, on an extraordinary basis, stamp duty payments made via bank transfer to the following IBAN: IT07Y0100003245348008120501.

If necessary, the following details can be added:

BIC code: BITAITRENT (which identifies the Bank of Italy);

Beneficiary: “Bilancio dello Stato” [State Budget].

In order to reconcile the transaction and connect the transfer to the application or to the document for which the stamp duty is due, in the payment description, the type and details of the application/document should be indicated, in addition to the tax code (or, if the tax code is not available, the name) of the person responsible for paying the stamp duty. Please make sure that all information provided is complete and accurate.

The company will have to provide evidence of the payment by sending the corresponding receipt, in order for AIFA to check to that the bank transfer has been correctly executed.

Please note that this method for paying the stamp duty, which is accepted under exceptional circumstances and on an extraordinary basis, is reserved only to foreign companies that do not have a local representative or an accredited attorney at AIFA. In all other cases, the payment should be carried out following the methods described in the above-mentioned notices.

Regardless of the method of payment used, the original documentation proving that the stamp duty has been paid (bank transfer, F23 form of the Italian Revenue Office, self-certification bearing a duly-cancelled paper revenue stamp) must be kept in the Applying company/Marketing Authorisation Holder’s file for any checks by AIFA.