

## **Information on applications for accreditation, revocation and communication of termination of the effects of power of attorney**

The following information is provided on applications for accreditation, revocation and communication of termination of the effects of power of attorney at the Italian Medicines Agency.

### **1. SUBMISSION OF APPLICATIONS**

Applications for accreditation, revocation or communication of termination of the effects of power of attorney shall be sent, via certified e-mail, to the certified e-mail address: [area.legale@pec.aifa.gov.it](mailto:area.legale@pec.aifa.gov.it).

Only foreign pharmaceutical companies or attorneys who wish to communicate the termination of the effects of a power of attorney, if they do not have a certified e-mail address directly referable to them, will be able to send submissions to the ordinary email address: [procuratori-aifa@aifa.gov.it](mailto:procuratori-aifa@aifa.gov.it).

If the documentation does not come from a certified e-mail address or from an e-mail address directly referable to the company concerned, it is essential, for the purposes of accreditation, to disclose at least the personal e-mail of the subscriber(s).

Applications for accreditation shall be accompanied by the accreditation form (Mod. 224/01) in the original Excel format, available on the institutional website. The form consists of three sheets plus the cover and shall be completed in all its parts - according to the indications of the relative manual - and sent together with the scan of the documentation accompanying the application, as specified below.

For administrative enquiries, please use the ordinary e-mail box: [procuratori-aifa@aifa.gov.it](mailto:procuratori-aifa@aifa.gov.it)

A special power of attorney or a simple power of attorney (delegation) may be granted, according to the principles set out below.

### **2. SPECIAL POWER OF ATTORNEY**

The special power of attorney shall be issued - by the pro tempore legal representative or by another person with the power to represent the company - with a notarial deed or with an authenticated private deed.

Please note that the authentication of the signature, even carried out by a foreign public official, in order to be valid in Italy, shall comply with the provision referred to in Article 2703 of the Italian Civil Code, and therefore, it is always necessary to first ascertain the identity of the subscriber as well as to have the express declaration of the public official concerning the fact that the document was signed in her/his presence: for instance, only authentication of signatures based on specimens or consisting of simple visas (e.g., the simple affixing of the notarial stamp or the use of the formula "*seen by me*" or similar) will therefore not be admitted.

If the special power of attorney has been drawn up by a foreign notary, it is necessary to legalise the signature of the signatory subject, pursuant to Sect. VI of the Presidential Decree no. 445 of 28 December 2000 (Consolidated Law on administrative documentation). The legalisation can be replaced by the affixing of the apostille for the deeds and documents issued in the countries adhering to the Hague Convention of 5 October 1961, ratified with Law no. 1253 of 20 December 1966. On the other hand, the deeds and documents issued in countries that have signed the Brussels Convention of 25 May 1987 on the abolition of the legalisation of documents in the Member States of the European Communities, ratified by Law no. 106

of 24 April 1990, are exempt from legalisation and apostille, as well as those issued in the countries that have signed a bilateral International Convention with Italy with the same tenor.

If the power of attorney or the supporting documentation (i.e.: chamber of commerce documents, shareholders' meeting resolutions, ...) has been drawn up in a foreign language, a certified translation shall also be attached to the application.

Moreover, please note that the special power of attorney shall be granted so that the attorney represents the company in AIFA, with full powers to carry out any act in the interest of the represented company, without exception. In any case, temporal limitations (duration of the effects of the power of attorney) as well as those concerning the possibility for the attorney to represent the company exclusively in relation to one or more pharmaceutical products are always allowed. These limitations, however, for the purposes of enforceability to the Agency, shall be explicitly provided for in the public deed or in the authenticated private deed with which the powers are conferred. On the other hand, if the company wishes to impose limitations on the power of attorney other than temporal ones or those related to pharmaceutical products (for example, limitations for matter or value or linked to a specific operational area), the power of attorney, while remaining valid, will not be accredited within the database of the Agency, so that the attorney will be required to show it every time s/he exercises her/his powers towards AIFA, in order to allow verification.

### **3. SIMPLE POWER OF ATTORNEY (DELEGATION)**

As regards the simple power of attorney (delegation), this is conferred by means of a substitutive declaration, pursuant to Chapter III, Section V of the Presidential Decree no. 445/2000, issued by the pro tempore legal representative or other person with the power of representation of the company. The granting of the delegation only entails the right to receive information, submit documents, sign receipts and collect any file, documentation and authorisation of the transferring Company from AIFA.

For the purposes of the accreditation of a simple power of attorney (delegation), only time limitations (duration of the power of attorney's effect) as well as those concerning the possibility for the attorney to represent the company exclusively in relation to one or more pharmaceutical products are allowed. These limitations, however, for the purposes of enforceability to the Agency, shall be explicitly provided for in the self-certification declaration with which powers are conferred.

Forms have been prepared for the granting of a simple power of attorney (delegation), pursuant to Article 48, paragraph 2 of Presidential Decree (D.P.R.) no. 445/2000. The substitutive declaration of certification can be signed with a handwritten or digital signature, while other types of signature will not be considered admissible (e.g. photographic reproductions of the signature).

Please note that a legible photocopy of a valid identification document of the declaring subject shall necessarily be attached to the self-signed declaration in lieu of certification.

As regards the signing of electronic documents, including the substitutive declaration of certification, please note that according to Article 20, paragraph 1bis of Legislative Decree 82/2005, the signing of the same can be legitimately carried out with a digital signature, qualified electronic signature or advanced electronic signature; in any case, for the purposes of the validity of the digital or electronic subscription, it is essential that the instrument used guarantees *"the security, integrity and immutability of the document and, in a clear and unequivocal manner, its traceability to the author"*.

Where the simple power of attorney (delegation) has been drawn up in a foreign language, please pay

attention to the need to attach the translation of the transfer deed to the power of attorney; the translation, on the other hand, will not be necessary where the company fills in the form Mod. 224/02 bis.

#### **4 SUB-DELEGATION**

In any case, the granting of the power of sub-delegation to the simple attorney (delegated) is not allowed.

The special power of attorney alone may expressly provide for the power of the attorney to delegate third parties only for the collection, from the competent AIFA offices, of correspondence, documents and/or deeds, as well as for the signing of the relative receipts; in any case, an implicit conferment of the power to sub-delegate is not accepted.

The special attorney, even with the powers of sub-delegation, will not in any case be granted the power to revoke attorneys appointed by other subjects, unless this specific right is expressly attributed to him.

The person endowed with representative powers (Managing Director, Chairman of the Board of Directors, CEO or equivalent) of a company that has the capacity of legal/local representative of another company, can expressly appoint special or simple attorneys (delegates) in the name of the company represented. The same person cannot revoke attorneys appointed by the company represented where this power has not been expressly provided for.

The limitations imposed on the special attorney with sub-delegation powers or on the legal/local representative, are invariably transferred to any sub-delegates, even in the absence of express provision.

Both in the case of appointment by the special attorney and by the legal/local representative, the termination of the power of attorney or representation, for whatever reason occurred, automatically results in the elimination of the power of attorney issued to the sub-delegate.

#### **5. REVOCATION OF THE SPECIAL OR SIMPLE POWER OF ATTORNEY (DELEGATION)**

The revocation of the special attorney or simple attorney (delegated), previously accredited, is ordered by means of a substitutive declaration of certification, issued by the legal representative or by the person with powers of representation, drawn up according to Form 224/03, to which it shall be attached the copy of a valid identification document of the signatory, except in the case of digital signature, according to the principles referred to in point 3 above.

Where the revocation act has been drawn up abroad or otherwise drafted in a foreign language, Companies are requested to pay attention to the need to attach the translation of the act to the revocation; the translation, on the other hand, will not be necessary where the company fills in Form 224/03bis.

The revocation may also be accompanied by the designation of a new attorney, through the simultaneous presentation of the forms and documentation indicated above for the purposes of accreditation.

For the revocation, it is not necessary in any case to attach the Excel file (Mod. 224/01).

#### **6. COMMUNICATION OF THE TERMINATION OF THE EFFECTS OF THE POWER OF ATTORNEY**

The previously accredited special or simple attorney (delegate), by substitutive declaration of notoriety, can communicate directly to the Agency the termination of the effects of a power of attorney concerning him. This communication can be drawn up according to Mod. 224/04 to which a copy of a valid identification

document of the signatory shall be attached, except in the case of digital signature, according to the principles referred to in point 3 above.

It is not necessary, however, to attach the accreditation Excel file (Mod. 224/01).

## **7. PROCESSING OF APPLICATIONS FOR ACCREDITATION OR REVOCATION**

The applications received will be processed in chronological order of receipt. In case of incomplete or inadequate applications and/or documentation, the appropriate integrations and/or changes will be requested, failing which the request will not be accepted.

Acknowledgement of accreditation, revocation and communication of termination of the effects of a power of attorney is given through the same certified e-mail box, by replying to both the sender and all copied addresses.