

**REQUEST FOR CERTIFICATE OF ACTIVE SUBSTANCE USED IN MEDICINAL PRODUCT WHICH HAS NOT BEEN GRANTED A MARKETING AUTHORIZATION IN ITALY AND DESTINED EXCLUSIVELY FOR EXPORT**

*(A revenue stamp<sup>1</sup> to be canceled by affixing, part on the brand and part on the sheet, the subscription or the date, or by affixing a stamp)*

To: AIFA  
Ufficio Ispezioni e Autorizzazioni  
GMP Materie Prime  
[protocollo@pec.aifa.gov.it](mailto:protocollo@pec.aifa.gov.it)

**Subject:** Request for n. \_\_\_\_\_ copy(ies) of certificate(s) of active substance(s) used in medicinal product(s) conformed to the format recommended by the World of Health Organization (WHO) for medicinal products which has not been granted a marketing authorization in Italy and destined exclusively for export.

I \_\_\_\_\_, born in \_\_\_\_\_,  
on \_\_\_\_\_, in accordance with articles 46 and 47 of d.p.r. 28.12.2000, n. 445,

**HEREBY DECLARE**

- Of being the Legal Representative/delegate<sup>2</sup> of \_\_\_\_\_ which manufacturing site is in (full address) \_\_\_\_\_, tel. n. \_\_\_\_\_, fax \_\_\_\_\_, legal headquarters in \_\_\_\_\_ (full address) \_\_\_\_\_;
- Of being aware that false acts and declarations are punishable by law and that, if such declaration is in fact found to be false, the declarer will no longer have any benefits consequent to the false declaration act, as prescribed by articles 75 and 76 of said act
- that the documents contained on CD/USB Drive, originally formed on analog support, comply with the originals documents according to d.lgs. n. 82/2005 (Digital Administration Code) and the d.p.r. of 28 December 2000 n. 445.

**HEREBY ASK**

The release of n. \_\_\_\_\_ copy(ies) of certificate(s) certificate(s) relative to the active substance(s) \_\_\_\_\_ in accordance with article 156 of d.l. 24 April 2006, n. 219, and the “WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation”.

<sup>1</sup>or € 16.00 to be paid on the AIFA bank account

Attachments to the present document:

1. Model certificate of active substance used in medicinal product, filled out in its entirety in English language, with particular regard to the reasons why the marketing authorization has not been granted in Italy;
  2. GMP certificate(s) of the manufacturer(s) of the active substance;
  3. Copy of the marketing authorization of the importing country or any documentation released by the competent authority certifying that the active substance is under evaluation for one of the following regulatory procedures: registration, renewal, variation, revision<sup>2</sup>;
  4. payment receipt<sup>3</sup>
  5. payment receipt of the revenue stamps due for the request of the certificate and for the certificate (see instruction of payment).
- digital copy of mod. F23 and related payment receipt<sup>4</sup>
- scanned self-certification with revenue stamps<sup>5</sup>
- Only for the foreign companies that do not have a local representative or an accredited attorney at AIFA: payment receipt of the bank transfer (see instruction of payment)<sup>6</sup>

With the present document the applicant

**DECLARES:**

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*2 This documentation must be presented according with the article 3, comma 4 of d.p.r.. 445/2000 art. 3 comma 4. For those countries which adhered to the Hague Convention of 5 October 1961, abolishing the requirement of legalisation for foreign public documents, the legal validity of documents issued by foreign authorities is ensured by the presence of an apostille.*

*3 The amount due is established by the decree dated December 6, 2016 (G.U. n. 25 of January 31, 2017). The payment has to be done in accordance with table published on the AIFA's institutional website, Italian section: Servizi Amministrativi/Versamento Tariffe e Diritti Annuali/Elenco Tariffe (H.7)*

*4 In case of request of more copies of a document, it is possible to pay the revenue stamps with a single mod. F23, calculating that the amount corresponding to the revenue stamps for the single document must be multiplied for the number of copies requested. The total amount should be reported in the section 13 "importo".*

*5 The Legal Representative/delegate shall purchase the revenue stamps, attach them on the self-certification (see template provided) reporting the serial numbers of the revenue stamps, cancel them by affixing, part on the brand and part on the sheet, the subscription or the date, or a stamp, then scan the self-certification (in pdf or jpeg, png format).*

*6 Only for the foreign companies that do not have a local representative or an accredited attorney at AIFA, the payment of the amount corresponding to the revenue stamps may be made by bank transfer to the following:*

*IBAN IT07Y0100003245348008120501*

*See instruction of payment.*

- a) that GMP standards identical to those recommended by WHO and laid down by the Italian legislation are applied to every batch of active substance object of this certification;
- b) that the access to the investigation report of possible quality defects is granted to the competent Authority of the importer's country even in the case the applicant is not the manufacturer of the active substance and specific agreement between the applicant and the manufacturer are in place;
- c) of being aware that all the information provided could be verified by AIFA.

In accordance to article 38, comma 3, of d.p.r. 28.12.2000, n. 445 a photocopy of proper identification must be attached to the present document.

Place and date \_\_\_\_\_

In witness  
(signature and stamp)

**REQUEST FOR AUTHENTIC COPY OF ACTIVE SUBSTANCE USED IN MEDICINAL PRODUCTS WHICH HAS NOT BEEN GRANTED A MARKETING AUTHORIZATION IN ITALY AND DESTINED EXCLUSIVELY FOR EXPORT.**

**(explanatory notes attached; general instructions can be found in the WHO guideline entitled “WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation”**

1	Applicant for certificate (name and address)	
2	Status of applicant: (according to category as defined in footnote <sup>2</sup> )	
3	Name of the pharmaceutical active substance <sup>3</sup>	
4	Importing country	
5	Name and address of the manufacturing site	
6	Provide complete reference to, and compliance with, pharmacopoeial monograph(s), where applicable and/or attached specifications	
7	Indicate Drug Master File or other references as applicable (e.g. CEP)	
8	Indicate if the pharmaceutical active substance subject to this certificate is used in pharmaceutical products registered for marketing in the exporting country	
9	Indicate category and name of the pharmaceutical product, if applicable <sup>4</sup>	
10	Indicate if the manufacturer complies with EU-GMP <sup>5</sup> (“Yes”, “No”, or “Not applicable”). Please specify if the answer is “No” or “Not applicable <sup>6</sup> ”	
11	Date of last inspection, if applicable	

Place and date \_\_\_\_\_

In witness  
(signature and stamp)

### **Explanatory notes**

1. *This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical active substance and of the applicant for the certificate in the exporting country. It is for a single active substance.*
2. *Use, whenever possible, International Non proprietary Names (INNs) or national non proprietary names.*
3. *Specify the manufacturer responsible for placing the pharmaceutical active substance on the market:*
  - a. *manufactures of the active substance;*
  - b. *repackages and/or relabels the active substance;*
  - c. *is not involved in any of the above.*
  - d. *Manufactures the active substance and further manufacturing sites may be involved.*
4. *List the dosage forms and categories. Examples are given below:*

<b>Pharmaceutical product(s):</b>	
<b>Dosage form(s):</b>	<b>Category(ies):</b>
Tablets	Citotoxic
	Hormone
	Penicillin
Injectables	Cefalosporin

5. *The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).*
6. *Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.*

## Instruction of payment

FEE:

Fee to be paid by bank transfer to the following bank accounts:

1) Bank account addressed to: Ministero della Salute

Amount: € 85,89 for each copy of the certificate

IBAN: IT 39A0760114500001004782767

Bank name: Poste Italiane Spa

SWIFT CODE: BPPIITRRXXX

2) Bank account addressed to: AIFA

Amount: € 26.47 for each copy of the certificate

IBAN: IT49E0503403200000000010448

Bank Name : Banco BPM S.p.a.

SWIFT CODE: BAPPIT21060 or BAPPIT22

### REVENUE STAMPS

1 Revenue stamp (€ 16,00) for the request + 2 revenue stamps (€ 16,00) for each copy of certificate to be paid.

**Only for the foreign companies that do not have a local representative or an accredited attorney at AIFA**, it will be accepted, 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: BITAITRRENT (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 of application 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 that the bank transfer has been correctly executed.

