

ASSIGNMENT FOR THE SIS CODES – OFFICIAL STATEMENT

In order to facilitate the procedure for the assignment of the SIS codes, starting from the May 2, 2011, all interested companies shall address specific application to the following e-mail account: sisdomanda@aifa.gov.it.

Each Company shall provide specific corporate information (see *SIS Code Data Form*) and the reason upon which the SIS code is requested, and attach - as provided by Circolare no. 9, 1997 - appropriate documentation, following the indications provided in the *Index* section below, according to the specific type of application.

Any required authentic documents shall be attached in PDF format to the application e-mail as well as sent via ordinary mail to the following address:

AGENZIA ITALIANA DEL FARMACO
Attribuzione Codice SIS
Via del Tritone no. 181
00187 Rome - ITALY

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1. Italian Pharmaceutical Companies which are/are to become MAHs and/or Manufacturers, and legal representative Companies

- Certified copy of company Statute and Deed of incorporation (or similar documents), o copy of the document enrolling the Company as a Public Organisation;
- certificate of the Chamber of Commerce, not older than three months, including information showing the Administrative Tribunal Certificate, Marketing Company Section, or a document released by a Public Organisation stating it does not have exclusively or mainly commercial activities;
- Tax Code and VAT number certificate;
- Statement signed by a legal representative providing an operating address for further correspondence.

2. Pharmaceutical companies established within the EEA wick are/are to become MAHs and/ or Manufacturers

- Certified copy of the Statute and of the Deed of incorporation of the Company in its own Country (or a similar document), in the original language and in Italian;
- Statement, in Italian (or in original language accompanied by a certified Italian translation), about a possible appointment of a representative company, duly signed by the company legal representative.

3. Pharmaceutical companies which are/are to become MAHs of medicinal products through EU procedures (Centralized, Mutual Recognition, Decentralized)

- For first time SIS code attributions: a copy of the European Commission Decision granting the MA through the centralised procedure and for which the national classification and negotiation procedures are being applied for;

or:

- Copy of the certificate of incorporation of the Company in its Country of origin (or a similar document), in the original language, or a copy of the registration issued by the Chamber of Commerce in the Country of origin, along with its Italian or English translation, reporting the registered office address;
- Indications on the operating offices address, if different from the registered address.

4. Concessionari di vendita (companies responsible for the actual placing on the market)

- Copy of the "concessione di vendita" Contract;
- Certified copy of the corporate Statute and Deed of incorporation (or a similar document);
- A Chamber of Commerce certificate, not older than three months, including information previously reported he Administrative Tribunal Certificate, Trading Companies Section;
- Tax Code and VAT number certificate.

5. Foreign Manufacturing Companies submitting Drug Master Files, and other Companies not included above

- Certified copy of the company Deed of incorporation (or a similar document) in the original language, or Chamber of Commerce certificate along with its Italian or English translation reporting the registered office address;
- An operating office address, whether different from the registered offices'.

Applicants shall immediately inform AIFA about any personal data variation. For Italian Companies, in case of Tax code modifications, it is mandatory to provide the complete new documentation and, consequently, the assignment of a new SIS code. For any other company data variation, regulatory procedures currently in force are confirmed.

For further information and/or clarifications, please contact: infosis@aifa.gov.it.

All personal data provided will be used with the unique aim of rendering the services requested and will be treated and stored in paper and electronic archives, according to the provisions set forth by Legislative Decree no. 196/2003 (Privacy Code).

SIS Code Data Form

Company	Holder (National Procedure) <input type="checkbox"/> Holder (Community procedures) <input type="checkbox"/> Manufacturer <input type="checkbox"/> ASMF Holder <input type="checkbox"/> Dealer <input type="checkbox"/> Legal Representative <input type="checkbox"/> Other (specify)
Foreign Company	Yes <input type="checkbox"/> No <input type="checkbox"/>
Foreign Country	
Tax Code (if applicable)	
Company Name	
Company abridged name (or trademark)	
e-mail	
Certified e-mail address (if applicable)	
Complete registered office address	
ZIP code	
City	
County/District	
Phone number	
FAX number	
Complete operating address (If it is different from legal address)	
City, (operating)	
ZIP code (operating)	
County/District (operating)	