

IMPORTANT NOTICE TO ALL PHARMACEUTICAL COMPANIES

APPOINTMENT OF COMPANY USERS ADMINISTRATOR

In the framework of the development of the new AIFA information system, it should be noted that as of today the companies concerned in online interaction with AIFA may appoint a "Company Users Administrator", hereinafter referred to as "CUA".

The appointed person, preferably an internal employee of the company, will have access to all applications for which a request was made during the registration process, as a representative of all the companies for which he/she has been appointed as CUA. The latter may also provide other users access to each application within the AIFA system, autonomously and without the intervention of the Agency.

Please note that:

- The CUA has access to all the applications requested during the registration process;
- The Company Users Administrator may authorize and/or revoke access by other users, to one or more AIFA applications, without any possibility for AIFA to intervene in the appointing and enabling process;
- The same person can be appointed as CUA for more than a company; in this case, it's necessary to fill an access to information systems form for each company (one form for each SIS Code);
- It is possible to appoint only one CUA for each company (one for each SIS Code);
- The same person can be both CUA and user of one or more applications for one or more companies other than the one for which it was appointed as CUA;
- More users for the same company may have access to each application;
- **The login credentials of the CUA are strictly personal and cannot be transferred to other persons or entities;**
- Any pharmaceutical company lacking a SIS Code has to preliminarily require the assignment of it by following the procedure specified at the following link:

http://www.agenziafarmaco.gov.it/sites/default/files/aifa_sis_en_apr2011_0.pdf

After obtaining the definitive SIS code, the company will be able to request CUA enablement according to the following instructions.

Please note that the users enabled since March 21st 2013, will maintain the validity of their access data, even in the case of a company lacking to appoint the CUA. Each company wishing to request cancellation of the enabled users or change the accessible applications, should follow the procedure for the appointment of the Company Users Administrator, as described below.

The legal representative of each company is the only person entitled to the appointment of the CUA, in consideration of the powers conferred and of the confidentiality of the data to which the Company Users Administrator has or gives access. For these reasons, other subjects, such as regulatory affairs managers, distributors, local representatives, holders of special proxy, etc... are excluded.

The Agency reserves the right to check the validity of the statements made, if necessary even through the acquisition of the certificate of incorporation of each company. In case the powers of the legal representatives, as described in the certificate, should not correspond to what is declared in the document appointing the CUA, AIFA will report it to the competent Court, according to Presidential Decree n. 445/2000.

In the case of companies with registered office abroad, the appointment of the Company Users Administrator may also be made by the legal representative of the company appointed to act as its representative in Italy. Please note that the abovementioned legal representation must be general and without limitation (it is not acceptable, for instance, if provided only for certain drugs or in relation to specific regulatory aspects), and it should be validated through appropriate documentation certifying the powers of representation (such powers should be supported by legalized official documents or self-certified declarations of the legal representative of the foreign company . A copy of the ID of the signatory shall, in this case, be provided).

The concerned companies are therefore invited to appoint their own Company Users Administrator following the registration procedure described here:

- 1) The legal representative of each company identifies the person that he intends to appoint as CUA, by filling the provided form in all of its parts;
- 2) The appointed person shall register on the dedicated AIFA front-end system, at the following address: <https://www.agenziafarmaco.gov.it/registrazione/>. By the end of the registration procedure, the user will receive two different e-mails containing his own username (which shall be reported in the dedicated line of the form) and a password.

Please note that users already registered since March 21st 2013, wishing to be appointed as CUA, should fill the provided form reporting username (i.e. name.surname) already received, and send by email the so completed form to AIFA, as described at point 3). In this case, the user shall NOT register another time.

Please also note that user previously enabled as CUA for a company, who wish to be enabled as CUA for another company, shall fill the application form reporting username (i.e. name.surname) already received and send it by email to AIFA, as described at point 3). Even in this case, the user shall NOT register another time.

- 3) The filled form referred to at point 1) shall then be submitted, together with a copy of a valid ID of the legal representative, duly dated and signed, exclusively via certified e-mail, to the following address: procuratori-aifa@aifa.mailcert.it; the transmission via ordinary e-mail is permitted only for foreign-based companies.

- 4) In case of companies with registered offices in Italy, certified e-mail address of the sender should be the official business address as resulting from the registration in the Chamber of Commerce.

IN ANY CASE, the e-mail subject, shall have the following wording: "Request to Enable Company Users Administrator – sis code – name of the company" **please note that sis code and name of the company are those of the requesting company;**

5) The Agency shall enable the CUA, by sending him an e-mail at the address upon registration;

6) Following the enablement, the Company Users Administrator may approve or reject requests to access each application forwarded by users who requested it, through the following link:

<https://servizionline.aifa.gov.it/>

In addition to the applications already available and in use, including the online payment platform, other applications will subsequently be available and duly described within specific online communications.

Please note that for any support and/or information, you may contact the helpdesk at the following e-mail: helpdesk@aifa.gov.it or call the number +39065032585 - Monday to Friday from 9:00 am to 6:00 pm.