



Certificates of a Pharmaceutical Product (CPP) signed electronically during the COVID-19 emergency

Marketing authorisation holders (MAHs) of medicinal products authorised via national, mutual-recognition, and decentralised procedures are hereby informed that on 17 March 2020 the Italian Medicines Agency (AIFA) introduced [new modalities](#) for submitting CPP applications, as subsequently [clarified](#) on 24 April 2020. Therefore, for any CPP application submitted through certified e-mail (PEC) or in paper format as of 17 March 2020, the electronically-signed CPP shall be sent via certified e-mail to the [digital address for service](#) indicated by the Company.

Electronic service of document is necessary because the Italian Medicines Agency (AIFA) is currently operating on the basis of teleworking. Additionally, a greater digitisation of the Agency's administrative procedures is being encouraged, for which reason AIFA reserves the right to assess the permanent adoption of such measures in the future.

The CPP form, which complies with the [WHO guidelines](#) and can be accessed at the following [link](#), is a document in PDF format and will carry the electronic signature (e-signature) of the [Certification and Parallel Import Procedures Office](#) Director.

The e-signature appended to the CPP guarantees the unique link with the signatory and the full authenticity and integrity of the document. The qualified electronic signature system used by AIFA is fully in line with EU eIDAS Regulation (European Union Regulation No. 910/2014) and with the Code of the Digital Administration adopted in Italy by Legislative Decree no. 82 of 7 March 2005, as amended and integrated.

Authenticity of the e-signature can be easily verified using specific software tools, such as the signature validation tool provided by the [DSS Demonstration WebApp](#).

Further information on the safety features of CPPs created and signed electronically is available in the [Guideline on the use of electronic signature verification tools](#).

Furthermore, a list of all CPPs issued will be published on the AIFA institutional website on a regular basis.

Finally, for issues concerning the validity of a certificate, the competent authorities of the destination country are invited to contact AIFA at any time at the following e-mail address cpp.aic@aifa.gov.it.