

Electronically-signed Certificates of Pharmaceutical Products (CPPs)

Marketing authorisation holders (MAHs) of medicinal products authorised via national, mutual-recognition, and decentralised procedures are hereby informed that CPP applications submitted through certified e-mail (PEC) shall be finalised with the issuance of an electronically-signed CPP. The e-signed CPP shall be sent via certified e-mail to the <u>digital address for service</u> indicated by the Company.

The CPP form, which complies with the WHO guidelines and is a document in PDF format, will carry the electronic signature (e-signature) of the Head of the <u>Certification and Parallel Import</u> Procedures Office.

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 (EU Regulation No. 910/2014) and with the Code of the Digital Administration adopted in Italy with Legislative Decree No. 82 of 7 March 2005, as amended and integrated.

The authenticity of the e-signature can be easily verified using specific software tools, such as the signature validation tool provided by the <u>DSS Demonstration WebApp</u>.

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