20 April 2021
EMA/206719/2020 Rev 1
Human Medicines Division

Information note on the format and validity features of electronic certificates for medicines issued by the European Medicines Agency.

As of Monday 30 March 2020, EMA has implemented a new system to issue electronically signed and authenticated certificates for human and veterinary medicines. For more information see our Press Release.

The aim of this ´Questions and Answers´ document is to provide guidance on the format of the electronic certificates issued by EMA, the safety features supporting their authenticity and integrity as well as the Agency´s measures to support the regulatory authorities of importing countries for confirming their validity, in case of any doubt.

Further details on the new electronic certificate system are provided below.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What does an electronic certificate look like?

Electronic certificates issued by EMA are electronically signed PDF documents that follow the same format layout and contain the same information as printed certificates.

The structure of certificates issued by EMA is:

- Pages 1-3 of English, Spanish and French (EN-ES-FR) multilingual certificates and pages 1-2 of certificates in Portuguese (PT) language contain, as per WHO recommendations, the information of the importing/requesting country; details of the medicinal product, the Community Marketing Authorisation and Marketing Authorisation Holder; administrative information, inspections and confirmation of conformity with Good Manufacturing Practice to the manufacturing site(s) of the medicinal product, as requested.
- Page 4 of EN-ES-FR multilingual certificates and page 2 of PT certificates include an electronic signature,
- From page 5 of EN-ES-FR multilingual certificates and page 3 of PT certificates, explanatory notes on the different sections of the certificates will be included.

This will be followed by the Annexes that will include the composition of medicinal product (if applicable) and the product information (as applicable).

The electronic certificates contain the Agency´s corporate identity features as a watermark on pages 1-4 for EN-ES-FR multilingual certificates and on pages 1-2 on PT certificates.

An example of pages 1-4 of an electronic EN-ES-FR multilingual certificate is available in Annex I.

What features does the electronic certificate contain to ensure its integrity and authenticity?

To assure the authenticity of EMA electronic certificates, each certificate contains an advanced electronic signature from a trusted provider fully compliant with the eIDAS Regulation (Regulation (EU) N°910/2014) that guarantees the unique link to the signatory and the full authenticity and integrity of the document. The Agency is using a certificate from a provider within the EU List of eIDAS Trusted Lists (LOTL).

The advanced electronic signature meets the following requirements: it is uniquely linked to the signatory; it is capable of identifying the signatory; it is created using electronic signature creation data that the signatory can, with a high level of confidence, use under his sole control; and it is linked to the data signed therewith in such a way that any subsequent change in the data is detectable. By certifying the PDF file, the electronic certificates are being "locked down" to detect unauthorised manipulation.

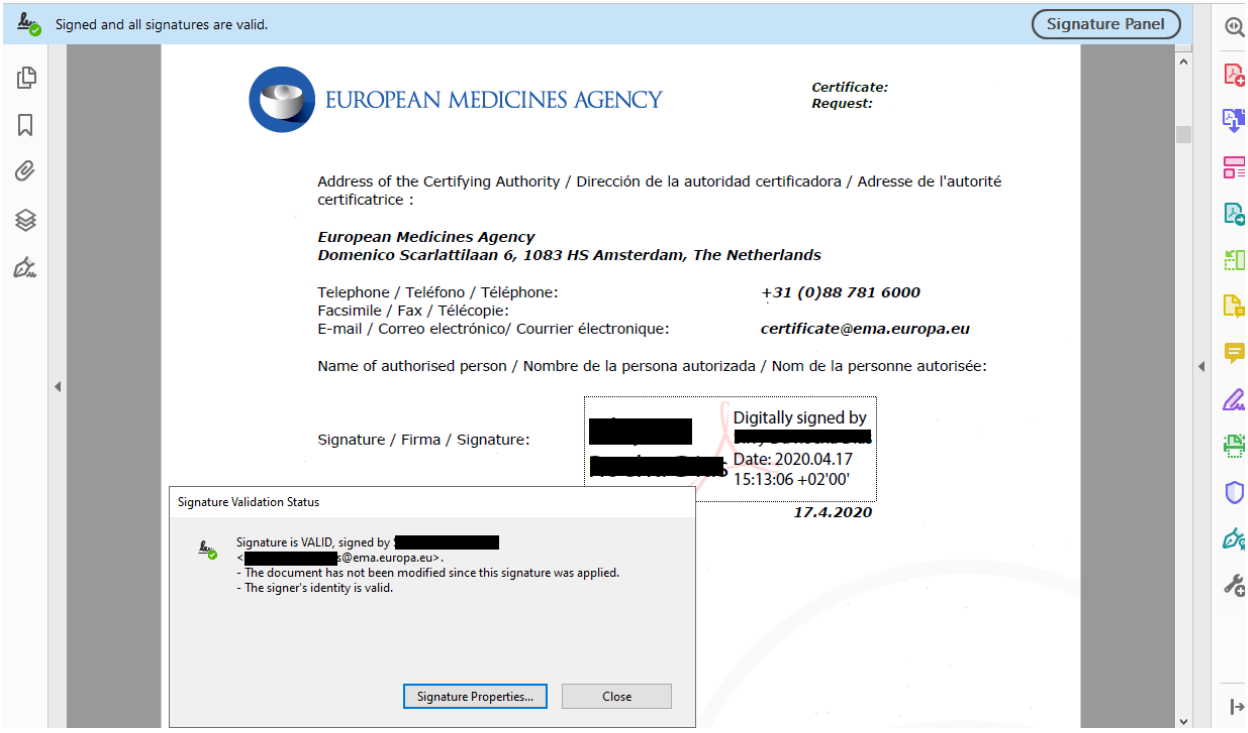
The EMA's electronic certificates and the electronic signature have been tested using Adobe Acrobat Reader. However, they are designed to be compatible with other PDF compliant applications.

Valid electronic certificate & signature

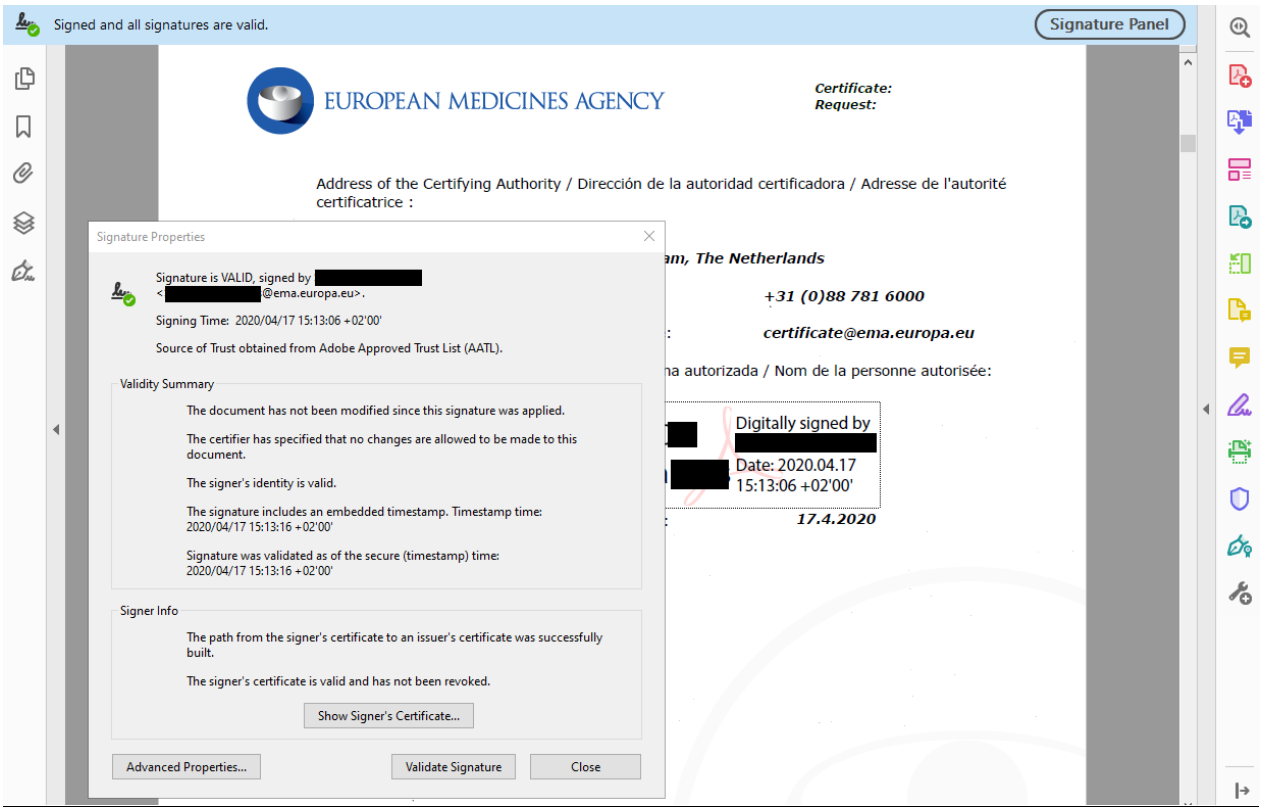
When opening the signed electronic certificate with Adobe Acrobat Reader, a ´Signature panel´ ribbon will appear on the on top of the document with the message: "Signed and all signatures are valid."

Clicking on the electronic signature itself, a pop-up window will appear confirming that the signature is valid stating the name and email address of the signing person; that the document has not been modified since it was signed and that the signer´s identity is valid.

Figure 1. Example of valid electronic certificate and signature



When clicking on the ´Signature properties´ button, a pop-up window will confirm that the signature includes an embedded timestamp, that the signature was validated as of the secure (timestamp time) and that a path from the signers' certificate to the issuer´s certificate was successfully established. This window also confirms the validity of the signer certificate (see message below displayed).

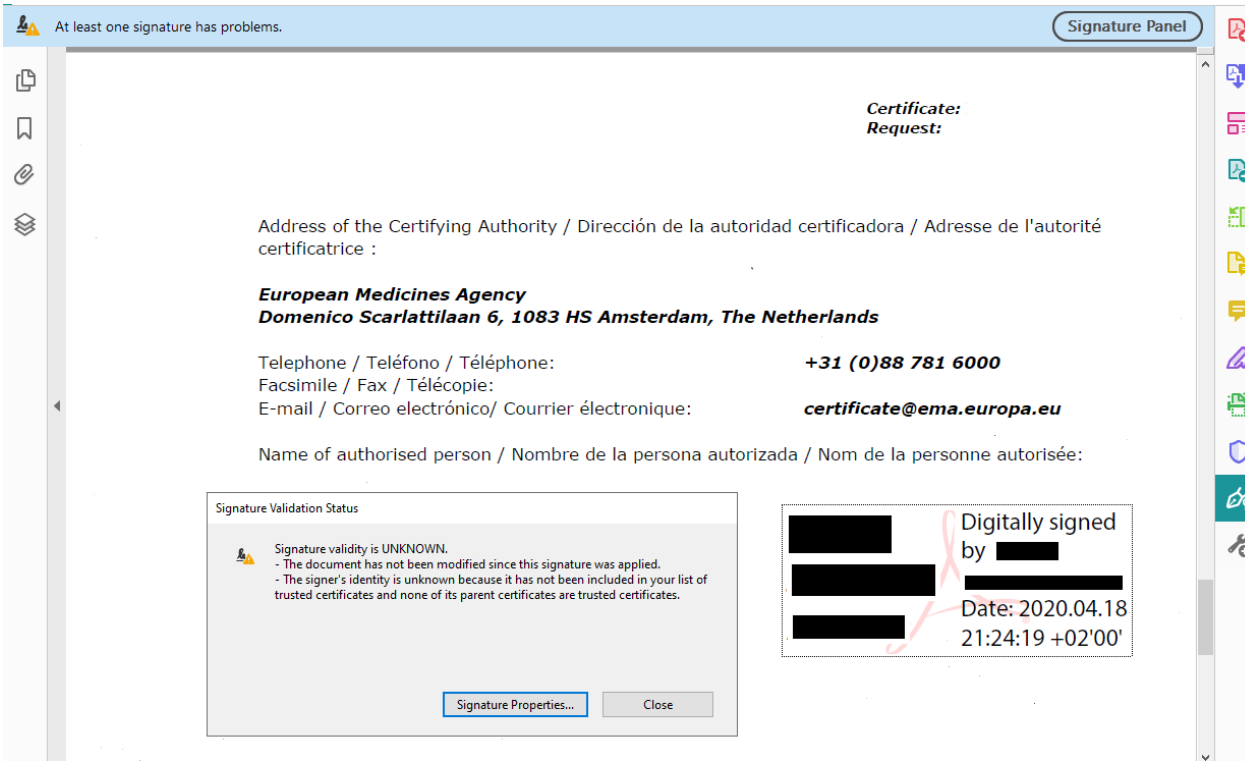


Example of a non-valid electronic certificate including a signature from an untrusted source

When opening a signed electronic certificate where the signature is from an untrusted source with Adobe Acrobat Reader or equivalent software, a ´Signature panel´ ribbon will appear on top of the document with the message: "At least one signature has problems".

Clicking on the electronic signature itself, a pop-up window will appear alerting that the validity of the signature is unknown, as shown in the image below.

Figure 2. Example of a non-valid electronic certificate and signature



For the correct display, please ensure to use the latest or a recent version of the Adobe Acrobat Reader or equivalent software.

What additional measures does the Agency provide to support the authenticity of the electronic certificate?

Along with the electronic certificate(s), the Agency provides in each request, a signed letter from the Executive Director of the European Medicines Agency detailing all staff of the European Medicines Agency authorised to sign electronic certificates.

The electronic certificates issued by the Agency can only be electronically signed by one of the authorised members in the letter.

In case of doubt, how can I confirm the authenticity or integrity of the electronic certificate issued by EMA?

In case of any doubt on the authenticity or integrity of electronic certificates issued by EMA, regulatory authorities of importing countries, MAHs or any interested party can verify their authenticity in the verification system published on EMA website. Upon inclusion of the unique numbers for the certificate and the request -both located in the first page of the electronic certificates issued by EMA-, the online verification tool will confirm its validity and display some details of the certificate (e.g. country of importation, medicinal product and pharmaceutical form, issuing date, signatory person).

Any additional query can be addressed to the Agency by email to certificate@ema.europa.eu.

The Agency aims to reply as soon as possible in accordance with the timelines for requests for information as described in the EMA Agency Code of Good Administrative Behaviour. The current response time for these requests at the time of publication of this notice is 2 working days.

How will my electronic certificate be dispatched?

Electronic certificates will be mailed to the applicant or designated recipient via our secure document mailing system EudraLink. You will need to have a EudraLink account to be able to receive certificates. If you do not have a EudraLink account yet, please request it via the EMA service desk.

In order to access the EMA service desk and request access to EudraLink you will need to create an EMA account. Please follow the instructions under "Create a new EMA account" in this link: https://register.ema.europa.eu/identityiq/login.jsf.

Once the EMA account has been created and you have received your credentials you can request a EudraLink account in the following link: https://servicedesk.ema.europa.eu/ (Click on 'Request a service', choose 'Access, permission, content updates and password requests', compile the request and attach a completed EudraLink request form available online under https://www.ema.europa.eu/en/documents/template-form/eudralink-account-request-form_en.doc and click on ´Create´).

Annex I

An example of pages 1-4 of an electronic multilingual English, Spanish and French multilingual certificate

Certificate of a Medicinal Product[1]
Certificado de Medicamento[1]
Certificat de Médicament[1]

This Certificate conforms to the format recommended by the World Health Organization. (Explanatory notes attached) / El presente certificado se adapta al formato recomendado por la Organización Mundial de la Salud. (Se adjuntan notas explicativas) / Ce Certificat est conforme à la présentation recommandée par l'Organisation Mondiale de la Santé. (Voir notes explicatives ci-jointes)

No. of Certificate / N° de certificado / N° du certificat: ***XX/XX/XXXXXX***

Exporting (Certifying) region / Región exportadora (que certifica) / Région d'exportation (certificateur) :
European Union / Unión Europea / Union Européenne :

Belgium, Bulgaria, Czechia, Denmark, Germany, Estonia, Ireland, Greece, Spain, France, Croatia, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, Finland, Sweden and United Kingdom (Northern Ireland).

Bélgica, Bulgaria, Chequia, Dinamarca, Alemania, Estonia, Irlanda, Grecia, España, Francia, Croacia, Italia, Chipre, Letonia, Lituania, Luxemburgo, Hungría, Malta, Paises Bajos, Austria, Polonia, Portugal, Rumanía, Eslovenia, Eslovaquia, Finlandia, Suecia y Reino Unido (Irlanda del Norte).

Belgique, Bulgarie, Tchéquie, Danemark, Allemagne, Estonie, Irlande, Grèce, Espagne, France, Croatie, Italie, Chypre, Lettonie, Lituanie, Luxembourg, Hongrie, Malte, Pays-Bas, Autriche, Pologne, Portugal, Roumanie, Slovénie, Slovaquie, Finlande, Suède et Royaume-Uni (Irlande du Nord).

For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI. / Para el Reino Unido, desde el 1.1.2021, el Derecho de la UE es aplicable al territorio de Irlanda del Norte (IN) según lo estipulado en el Protocolo de Irlanda/IN. / Pour le Royaume-Uni, à partir du 1.1.2021, le droit de l'UE s'applique uniquement au territoire d'Irlande du Nord (IN) dans la mesure prévue par le Protocole sur l'Irlande/IN.

Importing (requesting) country / País importador (solicitante) / Pays importateur (sollicitant):

XXXXXXXX

1 Name and pharmaceutical form of the product / Nombre y forma farmaceútica del medicamento / Dénomination et forme pharmaceutique du médicament:

XXX Film-coated tablet

1.1 Active substance(s)[2] and amount(s) per unit dose or unit volume[3]:
Principio(s) activo(s)[2] y cantidad(es) por unidad de dosis o unidad de volumen[3]:
Substance(s) active(s)[2] et quantité(s) par unité de dose ou unité de volume[3]:

XXX; XX mg

For complete composition including excipients, see attached. [4]/ Para la composición completa incluidos los excipientes, véase información anexa. [4] / La composition complète du médicament, y compris les excipients, voir annexe. [4]

1.2 Is this product subject to a Community Marketing Authorisation? [5]
¿Está sujeto este medicamento a una autorización de comercialización comunitaria? [5]
Ce médicament fait-il l'objet d'une autorisation communautaire de mise sur le marché ? [5]

yes

Confidential

1.3 Is this product actually on the market in the exporting region?
¿Se encuentra este medicamento en el mercado de la región exportadora?
Ce médicament est- il actuellement commercialisé dans la région exportatrice?

yes

2.1 Number in the Community Register of Medicinal Products [7] and date of issue:
Número de autorización de comercialización comunitaria [7] y fecha de emisión:
Numéro au registre communautaire de mise sur le marché [7] et date de délivrance:

EU/1/XX/XXX, XX.X.20XX

2.2 Community Marketing Authorisation Holder (name and address):
Titular de la autorización de comercialización comunitaria (nombre y dirección):
Titulaire de l'autorisation communautaire de mise sur le marché (nom et adresse) :

2.3 Status of the Community Marketing Authorisation Holder: [8]
Estatus del titular de la autorización de comercialización comunitaria: [8]
Statut du titulaire de l'autorisation communautaire de mise sur le marché : [8]

c

2.3.1 For categories (b) and (c) the name and address of the manufacturer producing the pharmaceutical form is: [9]
Para las categorías (b) y (c), el nombre y dirección del fabricante que produce la forma farmaceútica es: [9]
Pour les catégories (b) et (c), nom et l'adresse du fabricant de la forme pharmaceutique considérée : [9]

XXXXXXXXXX

2.4 Is the European Public Assessment Report (EPAR) appended? [10]
¿Se adjunta el informe europeo público de evaluación (EPAR)? [10]
Un rapport européen public d'evaluation (EPAR) est-il annexé ? [10]

no

2.5 Is the attached, officially approved product information included in the Community Marketing Authorisation?[11]
¿Se incluye la información sobre el medicamento adjunto en la autorización de comercialización comunitaria?[11]
L'information sur le médicament, officiellement approuvée, fait elle partie de l'autorisation communautaire de mise sur le marché ? [11]

yes

European Medicines Agency • Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Telephone +31 (0)88 781 6000
E-mail certificate@ema.europa.eu **Website** www.ema.europa.eu

2.6 Applicant for the Certificate, if different from the Community Marketing Authorisation Holder (name and address): [12]
Solicitante del Certificado, si es diferente del titular de la autorización de comercialización comunitaria (nombre y dirección): [12]
Demandeur du Certificat, s'il est autre que le titulaire de l'autorisation communautaire de mise sur le marché (nom et adresse) : [12]

3. Does the Certifying Authority arrange for periodic inspections of the manufacturing site in which the pharmaceutical form is produced?
¿La autoridad certificadora, dispone la inspección periódica de la planta de fabricación en que se produce la forma farmaceútica?
L'autorité certificatrice organise-t-elle des inspections périodiques de l'usine de production de la forme pharmaceutique?

yes

If no or not applicable, proceed to question 4 / Si no o no aplicable, pase a la pregunta 4 / Si la réponse est non ou sans objet, passer à la question 4.

3.1 Periodicity of routine inspections: ***Frequency of inspections is determined on risk-based approach.***
Periodicidad de las inspecciones de rutina: ***La frecuencia de las inspecciones esta basada en función del riesgo.***
Périodicité des inspections de routine: ***L'évaluation du risque détermine la fréquence des inspections.***

3.2 Has the manufacture of this type of pharmaceutical form been inspected?
¿Se ha inspeccionado la fabricación de este tipo de forma farmaceútica?
La fabrication de ce type de forme pharmaceutique a-t-elle fait l'objet d'une inspection?

yes

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization? [15]
¿Se adaptan las instalaciones y procedimientos a las GMP recomendadas por la Organización Mundial de la Salud? [15]
Est-ce que l'établissement pharmaceutique est conforme aux BPF recommandées par l'Organisation Mondiale de la Santé ? [15]

yes

4. Does the information submitted by the applicant satisfy the Certifying Authority on all aspects of the manufacture of the product undertaken by another party? [16]
¿La información presentada por el solicitante satisface a la autoridad de certificación en relación a todos los aspectos de la fabricación del medicamento realizada por terceros? [16]
Les informations fournies par le demandeur satisfont-elles aux exigences des autorités certificatrices sur tous les aspects de la fabrication du médicament pris en charge par une tierce partie ? [16]

yes

Confidential

Address of the Certifying Authority / Dirección de la autoridad certificadora / Adresse de l'autorité certificatrice :

European Medicines Agency
Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands

Telephone / Teléfono / Téléphone: ***+31 (0)88 781 6000***
Facsimile / Fax / Télécopie:
E-mail / Correo electrónico/ Courrier électronique: ***certificate@ema.europa.eu***

Name of authorised person / Nombre de la persona autorizada / Nom de la personne autorisée:

Signature / Firma / Signature:

Stamp and date / Sello y fecha / Tampon et date:

Confidential