FAQ

This document summarises key questions and answers raised by participants during a webinar organized in October 2022 on new policies, procedures, and trends in use of electronic Certificate of Pharmaceutical Product (eCPP), to support regulators worldwide to adapt their national procedures to streamline the use of eCPP, when applicable. Some questions may have been edited or regrouped for clarity. These answers have been provided for more information, but do not engage the responsibility of the webinar organizers or panellists.

Legalisation

Question	Answers
What steps are WHO, industry taking to encourage national regulatory authorities to remove the requirement of legalising CPPs or electronically-issued CPPs?	The Certificate of Pharmaceutical Product (CPP) is a document issued by a country's regulatory authority at the request of a product owner to support the registration process of a pharmaceutical product of another regulatory authority in a different country. The CPP confirms: • the approval from the referenced national regulatory authority was based on a full evaluation of the product's quality, safety and efficacy; • the product is manufactured under good manufacturing practices; and/or • the registration and marketing status of the product in the certifying country With the increasing number of CPPs required for regulatory submissions generating an administrative burden for both regulators and industry, and with the evolution of digital technologies, the use and acceptance of electronic CPPs (eCPPs) should be encouraged.

	The eCPP should be fully integrated with other digital systems used for dossier submission and review, including e-signatures and electronic dossier submissions. Appropriate international security standards for electronic signatures should be in place to ensure the authenticity of digital documents, including eCPP. This would made additional legalization of the eCPP redundant. For many years, the pharmaceutical industry has been working closely with authorities issuing certificates of pharmaceutical products (such as the EMA or the US FDA) and the WHO to raise awareness with regulators and legislators on the usefulness of CPP and more recently to transition to the use of eCPPs. Advocacy is key to promote acceptance of CPP without the need of legalisation. Further information can be found: • WHO CPP QA document (see question: 3Q8) • CPP publications • Webinar on new procedures and policies for eCPP
What can be done to accelerate country legislation to remove legalisation requirements?	The question of removal of legalisation requirements should be addressed locally/regionally between regulatory authorities and their legislative bodies/ governments. Removing the requirement for legalisation of CPPs would bring substantial benefits to patients. This requirement can delay the provision and submission of a dossier by minimum weeks but in many cases months. Continuous dialog and collaboration between various stakeholders (WHO and e-CPP issuing authorities, regional/local trade associations) are key to investigate the acceptance of the eCPP without further legalisation. Apostille or legalisation is not supported by WHO, EMA and other CPP issuing Health Authorities. Therefore, more dialogue, involving local trade associations, with those countries that still request apostille is recommended.

Is it possible to legalise an e-CPP?	**As discussed during the webinar, panellists from EMA, WHO and UK MHRA, the legalisation of an eCPP is an unnecessary and often redundant step that delays processes.** **Some agencies have already put in place new legislation and guidance which permits the acceptance of eCPPs without legalisation if the issuing authority has an online validation tool (as presented by the representative from the Egyptian MOH during the webinar). Some verification tools where regulators and the industry can verify the authenticity of electronic certificates can be found in the following NRAs websites:** • **The EMA (Authenticity verification for electronic certificates | European Medicines Agency (europa.eu)** • **The US FDA** • **The MHRA**
Will WHO make it mandatory for importing countries to accept non-legalised certificates?	**CPP is a voluntary scheme. WHO is an international organization and has no supra-national authority and, therefore, cannot require countries to accept non-legalised certificates. WHO will, however, continue to promote the benefits and integrity of electronic CPP without the need of legalisation.**
Will a statement be included in eCPPs that legalisation is not required as this document by nature is validated/authentic?	**There are no plans to include such statements, for further verification of eCPP validity. Issuing agencies have put in place online validation procedures, support publicity and communication exercises such as the event you attended, and all also provide contact points for receiving agencies to contact / discuss.**

Could EMA issue a document showing the position regarding the legalisation of CPP to argue to the local Health Authorities that they should not require it?	EMA has always advocated that the integrity and authenticity of eCPPs issued by EMA is guaranteed without the need for any additional legalisation. NRAs can check the authenticity of an eCPP issued by EMA by using the EMA online verification tool. EMA also offers the contact details of a focal point that recipient countries can reach out to. Although further legalisation of documents is considered a burdensome requirement by EMA and WHO, it is not in their remit to waive this requirement or define any necessary legal or technical changes to eliminate this national requirement. The certifying authority should officially stamp and date any certificates issued or certify using a secure electronic system/electronic certificate (e-certificate). Every effort should be made to ensure that certificates and all annexed documentation are consistent with the version of the marketing authorisation operative on the date of issue. Nevertheless, requesting authorities are discouraged to introduce legalisation procedures or any form of authentication procedures such as notarisation, embassy legalisation and apostillation that may cause the undue delay of certificates. EMA and WHO are encouraging the national competent authorities to undertake the necessary changes to allow acceptability of eCPPs and to consider the elimination of this requirement. See also: • WHO CPP QA document (see question: 3Q8) • WHO CPP Scheme (WHO TRS 1033 - 55th report of the WHO ECSPP - Annex 9, page 205, section 6.6)
To evolve to eCPP acceptance, is it necessary, as a "pre-work", that the importing countries have a well-	The eCPP should aid accelerating the overall assessment process and also favour interoperability with other digital systems. Some technical prerequisites to allow acceptance and processing of eCPP are welcome in the country requesting an eCPP, but these should not be a barrier for

established regulation on electronic signature?	the acceptance of eCPP. For instance there could be a phasing in the approach of adopting digital strategy from simple to complex system (e.g. accepting eCPP via email, direct access from issuing CPP NRA). As a natural evolution, each country should implement a comprehensive digital strategy that ensures interoperability between systems used for dossier submission and review, including e-signatures and electronic dossier submissions, where available. This will accelerate the overall review process. Moreover, once these technical prerequisites are met, requirements for providing hard copy documents should be waived. In addition, Health Authorities should harmonize electronic signature software acceptance such as DocuSign, to enable this to work effectively. The acceptance of electronic signature is a must in the new digitalized world. See also: • IFPMA eCPP position paper.
Why further legalisation for eCPPs is not necessary? What are the points to be mentioned in a discussion with the local MoH?	The eCPP produced by issuing authorities (EMA, US FDA, MHRA) are produced in the WHO agreed format, they derive the required information from secure Agency databases which are supported by audited process to ensure consistency of population and continuity. The eCPPs themselves are generated in a secure system and have unique un-corruptible verification numbers assigned to them. Their content is assured by the clear, audited process and systems, accountability for the accuracy of content and security resides with the agencies, irrespective of personnel accountabilities and responsibilities. See IFPMA eCPP position paper – recommendation number 3 Additional legalisation (by the Consulate or Embassy) should not be required, as it is beyond the international rules for the exchange of certificates/documents and it does not provide any enhanced evidence of authenticity. The CPP is a legal document that adheres to the principles of WHO that are endorsed by the majority of countries. Consulate legalisation is sometimes required, which is beyond the international rules for the exchange of certificates

	and documents as it does not provide any enhanced evidence of authenticity and does not provide additional value to patient safety. However, care must be taken to provide accepting authorities with timely and appropriate verification of the validity of certificates issued. For example, appropriate maintenance of membership of NRAs participating in the WHO Scheme is of utmost importance for preventing its misuse. In addition, required legal authentication leads to delays in CPP availability, impacting registration timelines and the availability of newly registered medicines to patients. Where a country requires a CPP prior to the approval of a product, Consulate/Embassy legalisation should therefore not be required since the CPP was issued by the NRA in accordance with the adopted WHO requirements. In addition, IFPMA in its position paper recommends to establish a concept of having CPPs issued for all NRAs who may require the CPP, rather than issuing CPPs for single, specified countries. The cost and resources used for obtaining CPPs have to be carefully managed in terms of ensuring timely access to safe medications. Where NRAs publish approvals online, details of approval on the official NRA's website can be used as proof of approval.
Will WHO be able to provide an eCPP declaration Letter to the Health Authorities, industries to validate the EMA, FDA etc, eCPPs, in order to avoid eCPP Legalisation process- Apostille?	As indicated in the WHO Technical Series Report 1033 – 55th ECSPP report – Annex 9 *Guidelines on the implementation of the WHO Certification Scheme on the quality of pharmaceutical* *products moving in international commerce* – section 6.6, WHO is not supporting the legalisation process.

Online Validation Tools

Question	Answers
Will WHO also recommend that NRAs issuing eCPPs develop and implement full online validation tools for the benefit of receiving NRAs?	The role of WHO is to raise awareness on the implementation of CPP/ eCPP and promote acceptance of eCPP without the need of legalisation.
Does all eCPP issuing NRAs provide authentication tool/service like EMA?	As of December 2022, only EMA and US FDA are providing such service. Other NRAs are strongly encouraged to consider implementing such procedure in the near future.
The EMA online verification tool provides limited information on the actual eCPP content, which may raise questions from receiving NRAs. In order to assure regarding full integrity and authenticity of eCPPs, will the EMA consider implementing an online tool through which receiving NRAs can validate full eCPP content (similar to the current FDA online tool)?	The online verification tool provides further assurance on the eCPP integrity and authenticity. Different territories have different legislation in relation to proprietary and confidential information. Under the current European legislation, it is not possible for EMA to publish the full CPP, since it contains commercially confidential information.
Does the MHRA intend to develop an online validation tool?	As of December 2022, the MHRA has not yet developed an online verification tool to check the authenticity of eCPPs. See MHRA website.

Will an online verification tool be available that can be used by the receiver without contacting the transmitter?	This is currently available from the EMA, and US FDA. Both have created webpages (see references below) which allows recipient authorities to validate eCPP without having to contact verbally or by email the issuers. References: • https://www.ema.europa.eu/en/human-regulatory/post-authorisation/certifying-medicinal-products/authenticity-verification-electronic-certificates • https://www.fda.gov/drugs/human-drug-exports/online-verification-ecpps-human-drug-products
Is it in the EMA pipeline to do a verification tool for other electronic documents such as GMP certificates? Do we still have legalisation issues for these documents?	No. Interested parties can consult the EudraGMP database for information on GMP certificates issued by European authorities (Eudra GMP - Public Layout (europa.eu).
Will a hyperlink in the eCPP issued by EMA be included for the verification tool to ease to check of the receiver?	EMA has no plans to include such hyperlink in every single certificate. The verification tool is easily accessible online. The EMA has also created an instructional flyer and YouTube video and provided extensive information in its website on the use of the verification tool.

Validity of eCPP

Question	Answers
What is the validity of eCPP issued by EMA?	The eCPP remains valid as long as there is no update on the Marketing Authorisation of the information stated in the eCPP or its annexes. Based on the scope of submission (e.g., variations), countries might request a new CPP. The certificates also confirm the good manufacturing practice (GMP) compliance status of the respective manufacturing site(s) The validity of the authorized e-signature can be checked on the EMA website.

Is there any procedure for renewal of eCPP on periodical basis by EMA? if yes then how often?	An eCPP cannot be renewed. However, based on the scope of submission (e.g., variations), countries might request a new CPP.
How can we check for previously issued CPP validity if it is withdrawn for any reason from the EMA website?	For any technical issues with the EMA verification tool for electronic certificates or if there are any concerns about the validity of an already issued certificate, please contact the EMA certificates team to request assistance (certificate@ema.europa.eu).

WHO Scheme revision and new format

Question	Answers
When WHO will update new CPP format, would EMA follow the new format immediately or not?	EMA confirms it has started issuing electronic Certificates of Medicinal Products (eCPPs) aligned with the new WHO template for requests received on or after 16th January 2023. All certificates are now being issued following the new template. Issuing certificates based on the old template is no longer possible.
Will the final WHO scheme lead to format & content change of current general CPPs?	The new WHO CPP scheme template has changes in content that were published in the 55th ECSPP report under Annex 9. WHO CPP Scheme - WHO TRS 1033 - 55th report of the WHO ECSPP - Annex 9, page 205
Some health authorities based in Latin America request the status of commercialisation in the CPP to assure that the product is being marketed in a reference country. Is this point to be removed in the future WHO CPP model?	In the new WHO template the status of commercialisation is not included. See link below also available in the 55th ECSPP report under Annex 9. See: WHO CPP Scheme - WHO TRS 1033 - 55th report of the WHO ECSPP - Annex 9, page 205
Does the WHO model of certificates ask for information about the shelf life and the presentation of the pharmaceutical form?	Shelf-life information is the 55th ECSPP report under Annex 9 and its Appendix 2 entitled *Model batch certificate of pharmaceutical products,* see section 5.3 In the new WHO model certificate, the shelf life cannot be added to the remarks section upon request. The pharmaceutical form will be captured in section 1:

	1. Name and dosage form of the product See: WHO CPP Scheme - WHO TRS 1033 - 55th report of the WHO ECSPP - Annex 9, Appendix 2 page 224

eCPP Software and database

Question	Answers
Do the Regulatory Agencies already implementing eCPP have any recommendations in terms of software/hardware requirements and any other resources for NRAs that would want to issue eCPP especially in the context of LMICs?	EMA cannot make recommendations on a particular software to be used, but it remains available to share the implementation experience with any interested authorities.
What measures or tools can be used to sign the CPPs electronically?	Please refer to this link for information on electronic signature on eCPP. Electronic signatures have unique number identification. As such, there is no need for additional signature on the document once issued. As an example, the EMA advance electronic signature complies with the EU regulation.
Are eCPPs linked to EMA SPOR database? If not, is there any implementation date to use EMA database for eCPPs?	The eCPPs are not currently linked to the EMA database and there are no such plans. In the future, site details in the EMA eCPP will match the information available in the EMA SPOR database. There are no timelines for implementation at this point.
Could someone not hack the pdf to unlock them?	Downloading a pdf is not recommended. The recommendation is to remain within the electronic envelope designed by FDA and EMA where you could scan a QR code or use a unique identification number to access the eCPP.

EMA and EDA specific questions

Question	Answers
Is EDA accepting eCPP issued from EMA only? or from any authority?	EDA is accepting all electronic CPPs as long as the issuing authority provides a tool for verification of the authenticity of this issued CPP, not only EMA CPP.
The following change will be implemented in EMA eCPPs: *EMA will only reflect the name and address of manufacturing sites in eCPPs as per SPOR data. The Agency may not be able to accept flexibility on local adaptations in the way of expressing the names or addresses*. Could you please clarify which will be the process to align the industry, plant sites, etc with the upcoming changes in EMA eCPPs?	In the future the information included in the eCPPs will be aligned with the EMA SPOR database. There are still no timelines by when this will happen, and appropriate guidance will be issued in due course.
For EMA, is there a fee for eCPP?	Yes, there is. The current fee structure is as follows: • €160 for standard request (10 working days turn around) • €480 for urgent (2 working days turn around). However, there is also €160 admin fee per request form for standard and € 480 admin fee per request form for urgent. So, one certificate will cost €320 (standard) or €960 (urgent).
Can anyone check the authenticity of eCPP in EMA website? If yes, may we have the link?	The ability to verify the authenticity of an EMA eCPP is publicly available via the following web-link: Authenticity verification for electronic certificates | European Medicines Agency (europa.eu). However, the certificate could only be accessed and verified by providing both the certificate number and the request number.

Countries

Question	Answers
Is the CPP still used by stringent regulatory authorities as it is used in developing and emerging markets?	No, the e-CPP or paper based CPP is not a requirement in countries where the regulatory authority has the capacity to undertake full independent quality, safety and efficacy (QSE) review. The use of the CPP (electronic or paper) is encouraged in developing countries as reliance tool and to assist developing agencies in releasing key scientific and trained resources to focus on other activities which could protect the public health. (e.g., increased counterfeit vigilance, import quality testing)
Is there any published website showing which countries accept eCPP without legalisation?	No. An official list doesn't exist.
What are the authorities who are adopting the eCPP?	The following regulatory authorities have adopted the eCPP: • EMA • US FDA • MHRA (UK) • Health Canada • AIFA (Italy) • INFARMED (Portugal) • Belgium NRA
How can we encourage other MoHs to fully transition to eCPPs?	WHO/IFPMA continue to provide support for the most efficient and effective use of CPP (and eCPP) by receiving agencies/MoH. Where possible industry and industry regional bodies should seek opportunity to highlight the availability, security and convenience of access to validation of the eCPP. The benefit to the patient should also be highlighted – use and acceptance of the eCPP potentially enables companies to submit weeks to months earlier than under the current

	paper CPP/legalisation/notarisation process. Earlier submission potentially allows earlier patient access to important new products.
Could all Health Authorities (HAs) that issue eCPPs adopt a harmonised practice (e.g., the authenticity information)? This would surely help all receiving HAs to trust and embrace eCPP further.	Each authority is currently only able to verify its own eCPPs. Harmonisation is an area to further explore and discuss with the eCPP issuing HAs.

Acceptance of e-signature

Question	Answers
Some countries are still reluctant to accepting e-signatures despite all of the efforts put out since the pandemic. What would your recommendations be if a company is confronted in this situation?	It is important to continue raise awareness, engage legislators, MoH and agencies to continue to provide clarity, insights and information on the use of eCPP and explain the benefits, highlighting that the electronic signature complies with well define local legislation (e.g., the EMA advance electronic signature complies with the EU regulation). Advocacy, information sessions, and continuous dialog between different stakeholders (WHO and eCPP issuing authorities, regional/local trade associations) are key to promote acceptance of eCPP.
Can WHO and EMA issue a joint statement recommending the acceptance of e-signatures (beyond eCPP?)	It is out of the scope of action for WHO to recommend acceptance of e-signatures beyond eCPP. WHO may issue a statement for acceptance of eCPP, formalizing what has been the WHO position in webinars and information sessions held. General recommendations on the use and acceptance of electronic signatures is beyond the EMA remit as medicines regulator.
What is the situation of acceptance of eCPP in South and Central America?	The majority of the South and Central America countries are accepting eCPP.

Would it be possible to WHO to issue a direct recommendation to LATAM Regulatory authorities to move forward with "reliance" efforts accepting eCPPs but also expanding the scope of the recommendation to other fields such as reliance on GMPs when issued by SRA?	WHO continuously recommends to all its Member States to use reliance as a regulatory tool in their national decision-making process.

Other

What are the timelines for getting e-CPP?	The timelines are indicated in the following respective regulators websites: • Certification of medicinal products | European Medicines Agency (europa.eu) Standard timeline: 10 working days. Urgent timeline: 2 working days • Health Canada CPPs Standard timeline: 25 business days. No expedited process. • FDA Export Certification | FDA Standard timeline: 20 business days. No expedited process. • MHRA Products | Home Standard timeline: 4 weeks. Urgent timeline: 7 working days

	• Portugal INFARMED Standard timeline: 1 month. No expedited process. • Certificates of pharmaceutical product with AIC | Italian Medicines Agency (aifa.gov.it) Standard timeline: 2 months. No expedited process
Does the issuance of eCPP warrant the GMP inspection of the manufacturing facility?	A health authority will only issue an eCPP for a manufacturing site that has a validated GMP inspection report.
Who can request an online eCPP? Can a third party request an eCPP?	To request an eCPP, a third party would need an authorisation and the appropriate level of information from the manufacturer. In addition, it should be noted that in some countries, the request must come from a person based locally.
Can an eCPP be issued for conditional approval?	The US FDA will not issue eCPP on conditional approval. The EMA is currently issuing eCPPs for products under conditional approval.
Will there be possibility in the future to have a QR code on the CPP that can be scanned to automatically check its validity etc?	WHO has only recommended the general format of the CPP. Issuing authorities are free to implement various tools and techniques (including QR code) to help authenticate the validity of certificates. It should be noted that the US FDA is already using the QR code system to check the validity of eCPPs. The EMA is currently using a different technology (online verification tool requiring unique reference numbers). IFPMA is encouraging Regulators and WHO to work together on the implementation of a common verification system.

Is it a better practice if an issuing authority publishes the full CPPs on their website instead of showing some summary data?	**Each Health Authority issuing CPPs have established their own practices according to their country legislation.**