New procedures and policies for the electronic Certificate of Pharmaceutical Product (eCPP)

What is a CPP and eCPP?

A Certificate of Pharmaceutical Product (CPP) is a documentation requested by foreign customers and governments assessing a facility's compliance with good manufacturing practice (GMP) and marketing authorization status when exporting medical products. The CPP was introduced as a tool to facilitate the regulatory review and to replace a full dossier evaluation of the Quality, Safety and Efficacy (QSE) in the importing country.

Paper certificates have been the common standard. However, with the COVID-19 pandemic having catalyzed a massive shift towards the use of electronic tools, some reference regulatory authorities have undergone a digital transformation journey and have introduced new procedures and policies for issuing electronic certificates of pharmaceutical product (eCPP).

Why is eCPP a solution to be widely implemented?

To avoid disruptions in the supply of medicines to patients and promote timely access to medicines, implementation of eCPP delivers fast and efficient services, overcoming trade disruption and streamlining the verification and authentication process of these certificates.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) conducted a survey in September - November 2021 with their regulatory networks on the acceptance of electronic certificates from the European Medicines Agency (EMA) and the usage of online verification tools. The survey reported that some regulators do not accept (14) or will accept them during the pandemic (24) and will require paper certificates once the pandemic is over.

This reflects the growing interest in eCPP to further promote timely access to medicines and vaccines and calls for further reflection on the need to adapt local practices to new ways of working, to rationalize and streamline the use of CPPs and eCPP and align local procedures to international best practices.

Perspectives shared by regulatory authorities during webinar on “New procedures and policies for the eCPP”

With the strong belief that the current challenges around electronic certificates might be addressed with further dialogue and clarification by reference regulators, a virtual platform for discussion brought together representatives from national regulatory authorities (NRAs), the World Health Organization (WHO), and pharmaceutical companies, to address new policies, procedures, and trends in the use of eCPP. It also aimed at supporting regulators worldwide to adapt their national procedures to streamline the use of eCPP, when applicable. This exchange of information proved beneficial to both regulators and companies, representing a clear area of cooperation between different stakeholders. The platform was created by EFPIA, IFPMA and the Pharmaceutical Research and Manufacturers of America (PhRMA) in October 2022.

The webinar touched upon the benefits of using eCPP through practical examples from the European Medicines Agency, the Egyptian Drug Authority, and the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK, as well as potential solutions for effective implementation.

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Key Takeaways

The CPP is a crucial document for regulatory submissions at international level. To avoid disruptions in the supply of medicines to patients and promote timely access to medicines, there is the need to promote awareness of the new global landscape for the electronic CPP.

The COVID-19 pandemic has introduced opportunities and challenges for regulators who issue and use paper CPPs. The eCPP concept proved extremely valuable in delivering fast and efficient services, paving the way towards broader implementation of the eCPP.

The eCPP should be fully integrated with other digital systems used for dossier submission and review, including e-signatures and electronic dossier submissions, rather than being handled as a standalone physical requirement.

The eCPP system is built on a reliable and secure method for verifying certificate authenticity. As security standards for electronic signatures and verification steps should be in place to ensure the authenticity of the eCPP, additional legalization of the eCPP by consulates or embassies should not be required.

Implementation of electronic certificates will support the increase in efficiency of regulatory systems, being a recognized reliance tool for all stakeholders, and will ultimately facilitate faster access to medicinal products to patients.

Worldwide implementation of electronic certificates is encouraged by leading authorities, such as the WHO, the EMA and the MHRA.

Why eCPP?

The World Health Organization (WHO) Perspective

Since the introduction of the WHO Certification Scheme - an administrative tool for exchange of information between national regulatory authorities - the regulatory landscape has widely changed.

Today, the higher number of exporting countries, the faster pace of communication and the challenges posed to the application of the certification scheme have caused the standard CPP system to lose its original role. An adaptation of the original CPP concept is therefore needed.

- The eCPP allows for faster communication and for easier information exchange and access.

Some NRAs have indicated that, during the COVID-19 crisis, they will no longer be in a position to issue and send paper copies of Certificates issued in the context of the WHO Certification scheme. Instead, a secure e-signature process will be used.

- The WHO agrees with this approach and recommends other regulators issuing certificates to consider this approach too. Moreover, NRAs receiving certificates are urged by the WHO to accept the electronic signature.
- The WHO will also implement a new CPP template by the end of 2022.

European Medicines Agency (EMA) Perspective

Digital transformation is a key priority area in the European Union and the EMA, with the eCPP being part of the agency's drive for digital transformation, increase efficiency, and reduction of paper usage and waste.

- Since March 2020, the EMA only issues electronic certificates, which made it possible for the agency to provide certificates during the COVID-19 pandemic without any business disruption and still facilitating the regulatory compliance and timely access for medicines in importing countries. The Agency considers eCPP as the permanent way of issuing certificates.
- The electronic signature and the online verification tool available on the EMA website make it possible for any importing authority to fully ensure the integrity, validity and authenticity of the eCPP issued by the EMA.
- The EMA encourages importing countries and NRAs to adapt their systems and update their respective legislation for fully accepting electronic certificates issued by the EMA.

The Egyptian Drug Authority (EDA) Perspective

According to the EDA regulations, the CPP is a mandatory document for the registration of any imported product. By summarizing all relevant data regarding the product, the CPP ensures that the regulatory authority approval was based on a full evaluation of the product's Quality, Safety & Efficacy; that the product is marketed in the CPP-issuing country (mandatory for products submitted for registration in Egypt); that the product is manufactured under GMP conditions and that it reflects all approved manufacturers of the product, concentration and presentation.

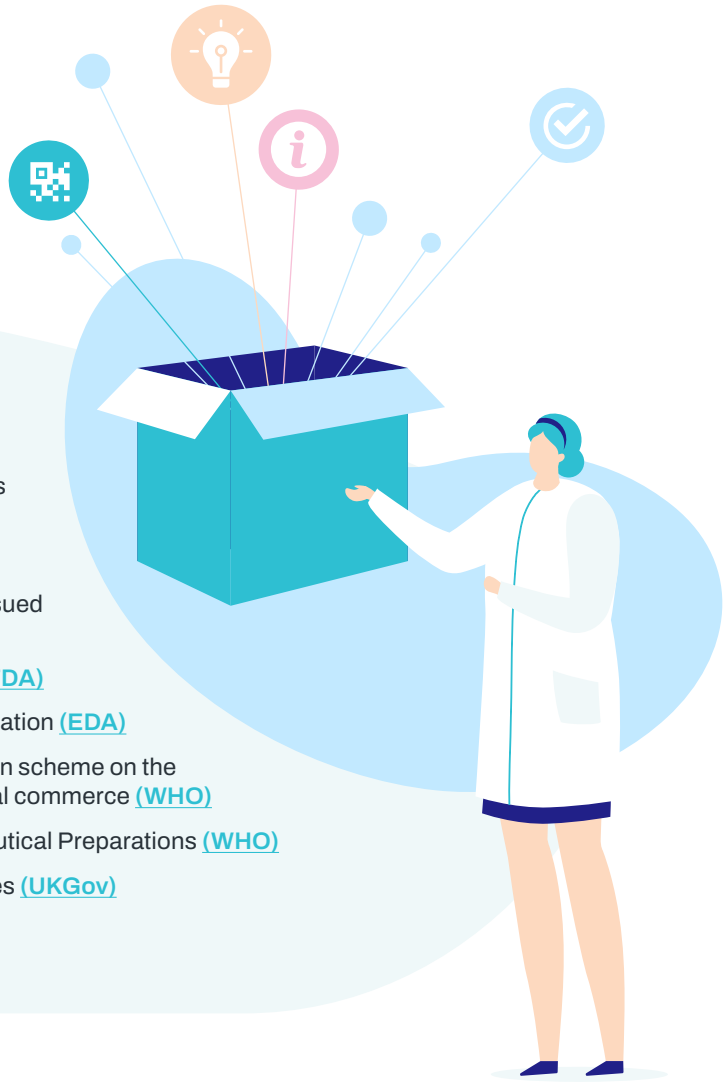
Forcing all processes to be digitalized, COVID-19 has introduced challenges for regulators and for the industry. Accordingly, the EDA decided to update their regulations, which now request that the original legalized CPP be transferred to eCPP format, as long as the issuing authority has a verification tool in place.

- Issuing eCPPs has improved efficiency in delivering certificates, reducing the time it takes to legalize them and for the submission of the registration dossier.
- The eCPP also allows quicker and easier verification from issuing authority and faster credentials verification by receiving authority, therefore allowing patients to have access to new medicines faster.
- Legalization of an eCPP should not be required, as its authenticity can be verified online through secure eCPP repositories.

The Medicines and Healthcare products Regulatory Agency (MHRA)

The MHRA now issues an electronic monthly register of eCPPs which can assist health authorities if further verification of the authenticity of the eCPP is required.

- The eCPP is issued as secure PDF document, and cannot be falsified without the receiving entity not realizing its lack of authenticity.
- Authorities can be contacted through email if required, for further verification steps.
- Hard copies of CPPs have not been provided since March 2020.
- In March 2020, the MHRA informed receiving authorities regarding the changes from paper to electronic CPPs, and each eCPP issued was accompanied by a cover letter containing new information regarding the new eCPP releasing procedures and verification system.
- The MHRA has introduced two new services: urgent eCPP service issuing a certificate within 2 days, and a standard one issuing certificates in 10 days.



Resources Box

- Information package for certificates of medicinal products issued by the European Medicines Agency (EMA)
- Authenticity verification for electronic certificates (EMA)
- How to check the authenticity of electronic certificates issued by the European Medicines Agency (YouTube)
- Online Verification of eCPPs for Human Drug Products (FDA)
- EDA announcement for eCPP acceptance without legalization (EDA)
- Guidelines on the Implementation of the WHO certification scheme on the quality of pharmaceutical products moving in international commerce (WHO)
- WHO Expert Committee on Specifications for Pharmaceutical Preparations (WHO)
- Human medicines: register of electronic export certificates (UKGov)
- IFPMA CPP network training toolkit (IFPMA)