EMA experience on eCPPs

EMA/Industry Platform meeting on Centralised Procedure. 3 December 2020

Presented by Alberto Ganan Jimenez
Head of Procedures Office
Committees and Quality Assurance Department. Human Medicines Division

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Introduction

- **Digital transformation** is a key priority area in the EU and the European Medicines Agency*.

- From 30th March 2020, **EMA** started to only issue **electronic certificates** for medicinal products (eCPPs). This ensured that EMA could provide certificates during the COVID-19 pandemic without any business disruption facilitating the regulatory compliance and timely access for medicines in importing countries.

- **WHO supports this initiative**, recommends other regulators issuing Certificates to consider this approach too and urged NRAs receiving Certificates to accept the electronic signature.

* Draft European Medicines Agencies Network Strategy to 2025

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EMA experience on eCPPs

- In 7.5 months of experience, EMA has issued 7733 eCPPs (30.03.20-12.11.20)
- The timeliness and high records on quality of the CPP has been maintained after implementation of eCPPs:
  - >99% of eCPPs issued on current handling times (2 / 30* working days for urgent/standard eCPPs respectively)
  - 77 eCPPs required any amendment
  - Only 2 reported case of errors linked with eSignature features.

	Number (n)	%	eCPPS issued late (n)*	%	eCPPs reissued (n)	%
Standard eCPPs	5630	73.4	17	0.3		
Urgent eCPPs	2063	26.6	21	1.0		
Total	7733	100	38	0.5	77	1.0

- The Agency is working towards a decrease on handling times for standard CPPs (curr. 12 days)

** The handling time for urgent eCPPs is 2 working days.*
The handling time for standard eCPPs is temporarily extended to 30 working days as per communication dated 19.10.2018

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EMA experience on eCPPs

- The Agency receives an average of 10-15 queries per week through EMA certificate mailbox mainly related to procedural aspects, confirmation from legalising bodies.
- Very limited number of requests to confirm the authenticity of an eCPPs from third countries. 149 CPPs requested confirmation from only 3 importing countries since March 2020. All requests have been replied within 2 working days.

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Main challenges for a worldwide implementation eCPPs

- Concerns on the **authenticity and integrity of CPPs** by some importing authorities
  - Many importing countries require further legalisation of CPPs although this requirement is not supported by WHO and EMA

- **Acceptability of the new electronic format**
  - Limited experience as there is a limited number of authorities issuing eCPPs
  - Legal and technical challenges: some importing authorities require adaptation of their local legislations and/or technical tools for accepting electronic submissions

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EMA measures to assure authenticity and integrity of eCPPs

Letter of authorisation

- Each request for eCPP is accompanied by a signed **letter of authorisation** from the EMA Executive Director detailing EMA staff authorised to sign eCPPs.

Public guidance

- On 20th April 2020, EMA published **specific guidance** on the features of eCPPs supporting the validity and integrity of the documents.

Direct communication

- EMA has established an **email address*** where receiving authorities can request **confirmation** of the authenticity or integrity of the eCPP. Current response time <2 days.

Online verification tool

- EMA is currently developing a **Web based tool** to directly confirm that a CPP has been issued by EMA.

- *certificate@ema.europa.eu

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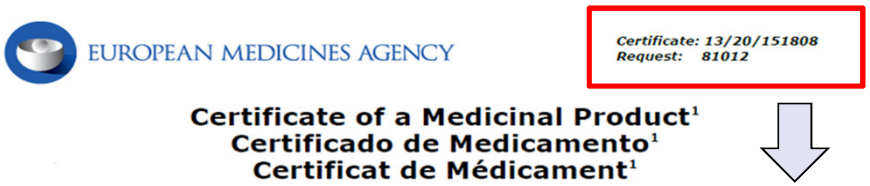
Online verification tool under development

- The Agency is developing a webtool (intended launch I QTR 2021) where applicants, third countries and any other interested party (e.g. legalisation authorities) can confirm the details of an eCPP issued any the Agency.
- Upon inclusion of the Request and certificate numbers of the eCPP, the tool will provide details of the certificate and confirm its validity.



Number of Certificate	Importing Country	Medicinal Product	Signed by	Issued on	Status
02/20/144556 77086	JORDAN	Capecitabine MAH Film-coated tablet	Adam Smith	08/05/20	VALID

- The tool will contain a safety feature to minimise the risk of unauthorised robot-based access to these details.

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EMA measures to support acceptability of eCPPs

International collaboration

- **International collaboration with WHO**. WHO highly supported the initiative, confirmed its compatibility with current WHO Certification Scheme and communicated on WHO webpage and directly to competent authorities participating in the scheme.

Share Experience with issuing authorities

- EMA has **shared experience to interested issuing authories** that have approached EMA and are considering the implementation of eCPPs.

Direct communication to receiving authorities

- EMA international Affairs Division sent **letters to ~70 receiving authorities not accepting eCPPs or accepting with restrictions** urging to implement the necessary changes to their NRA systems. These authorities were identifed following feedback from EFPIA / Vaccines Europe.
- EMA has provided letters in English and Spanish to MAHs confirming that EMA does not issue printed CPPs and urging third countries to adapt their regulatory systems.

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eCPPs and COVID-19 medicinal products

- EMA issues CPPs for authorised CAPs and also for CAPs that are **under consideration** by the Agency for a MAA.
- COVID-19 vaccines or products under a formal rolling review can also apply for CPPs of product ´under consideration´ by EMA.
- All information to be included in the CPP should have already been submitted in an eCTD sequence to the Agency as part of any of the rolling review cycle. This includes all the necessary data available to certify that the manufacturer(s) of the medicinal product holds a valid manufacturing authorisation or a valid GMP certificate.

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Next steps

- **EMA considers eCPPs as the permanent solution for issuing CPPs** as part of the Agency´s efforts to digitalise its administrative processes for all documents requiring signature.
- An online webtool to confirm validity of eCPPs is intended be launched in I QTR 2021 together with a direct communication to receiving authorities.
- **Most receiving authorities are accepting eCPPs** with / without additional measures. Limited concerns on authenticity of eCPPs based on the low number of confirmatory queries received by EMA.
- EMA is working towards a decrease in the handling time of standard certificates to 10 working days in support of a timely access of medicines -including COVID medicines- in importing countries.
- EMA will continue supporting the main drivers for a **worldwide implementation of electronic CPPs**: the implementation of eCPPs by other issuing authorities and the undertaking of the necessary legal/technical changes in NRA systems of receiving authorities.

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Any questions?

alberto.ganan@ema.europa.eu

certificate@ema.europa.eu

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Send us a question Go to www.ema.europa.eu/contact
Telephone +31 (0)88 781 6000

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