NEW PROCEDURES AND POLICIES FOR THE ELECTRONIC CERTIFICATE OF PHARMACEUTICAL PRODUCT (eCPP)

WELCOME

Presentations in English. Please click on the globe for French, Spanish or Portuguese.
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Apresentações em inglês. Clique no globo para interpretação em português.

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WHO’s recommendation for the use of eCPP

Samvel Azatyan
Team Lead, Regulatory Convergence and Networks at
World Health Organization

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Webinar on new procedures and policies for the electronic Certificate of Pharmaceutical Product (eCPP)

3 October 2022 (virtual)

Dr Samvel Azatyan
Team Lead, Regulatory Convergence and Networks
Team Lead a.i., Facilitated Product Introduction
Regulation and Safety Unit, Regulation and Prequalification Department
World Health Organization

WHO update: Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (CPP Scheme)

What is the WHO Certification Scheme

- Administrative tool for exchange of information between national regulatory authorities

Based on:

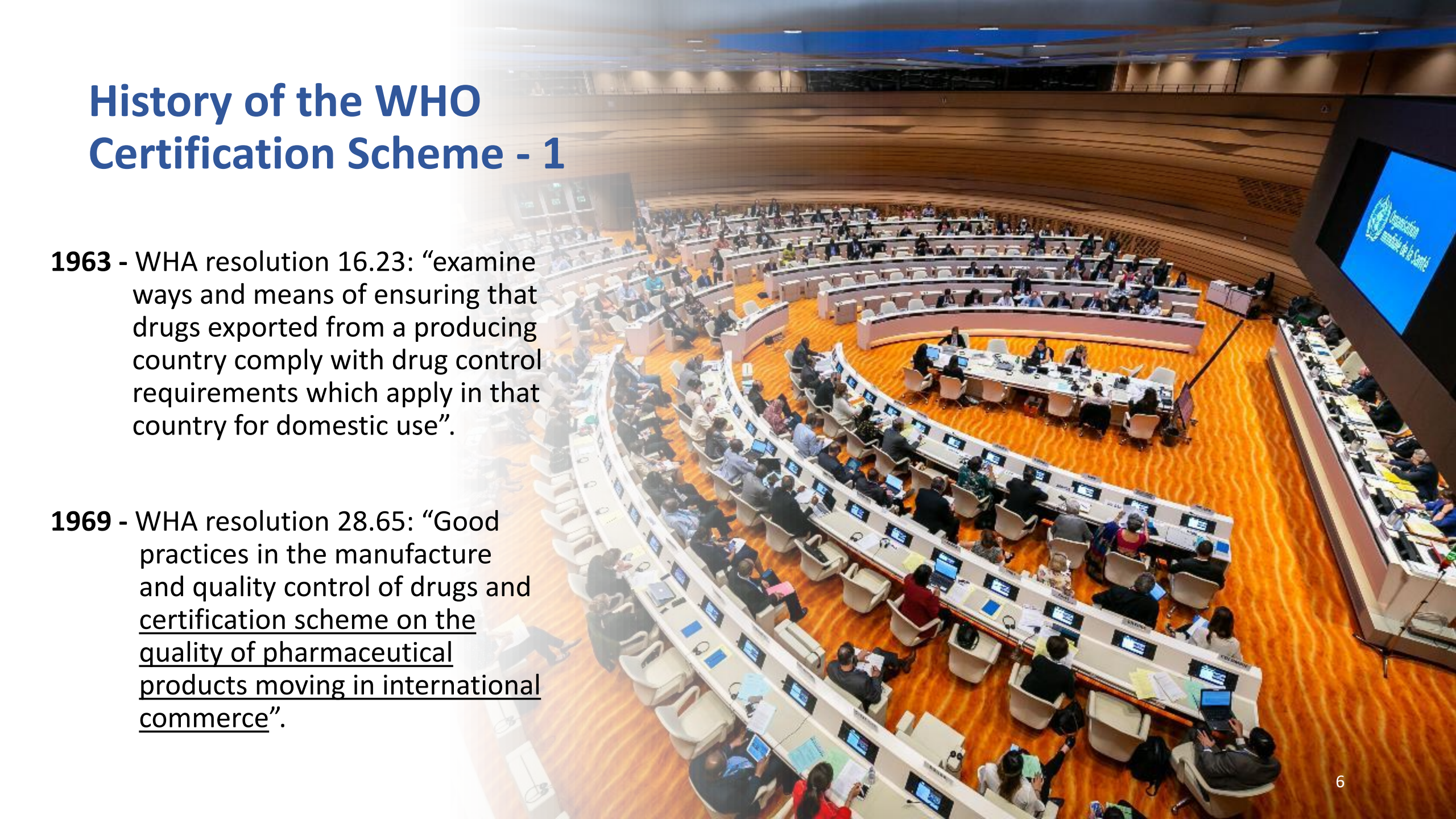
  - voluntary, non-binding agreement
  - self-assessment of regulatory capacity

- Intended to facilitate trade of pharmaceuticals of good quality, safety, and efficacy and to hinder international circulation of substandard products.

History of the WHO Certification Scheme - 1

1963 - WHA resolution 16.23: “examine ways and means of ensuring that drugs exported from a producing country comply with drug control requirements which apply in that country for domestic use”.

1969 - WHA resolution 28.65: “Good practices in the manufacture and quality control of drugs and certification scheme on the quality of pharmaceutical products moving in international commerce”.



History of the WHO Certification Scheme - 2

1975 revision added:

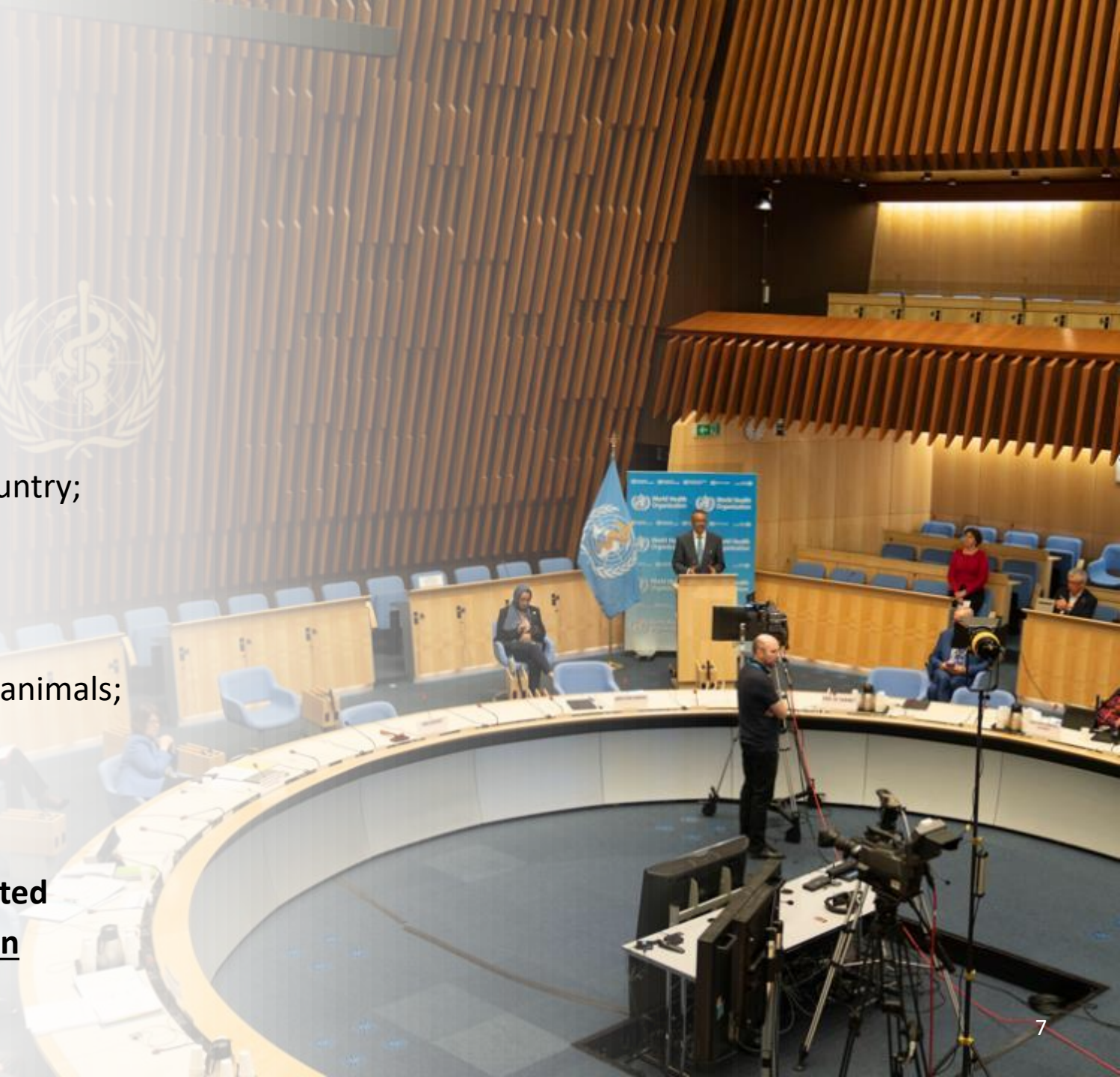
- regulatory status of product in exporting country;
- GMP compliance of manufacturing site.

1988 revision added:

- active ingredients;
- veterinary products used in food producing animals;
- product information and labelling.

1992 current version, operational since 1997

TRS1033: proposal for discussion, not yet submitted to WHA for endorsement, not for implementation



Participation in the WHO Certification Scheme

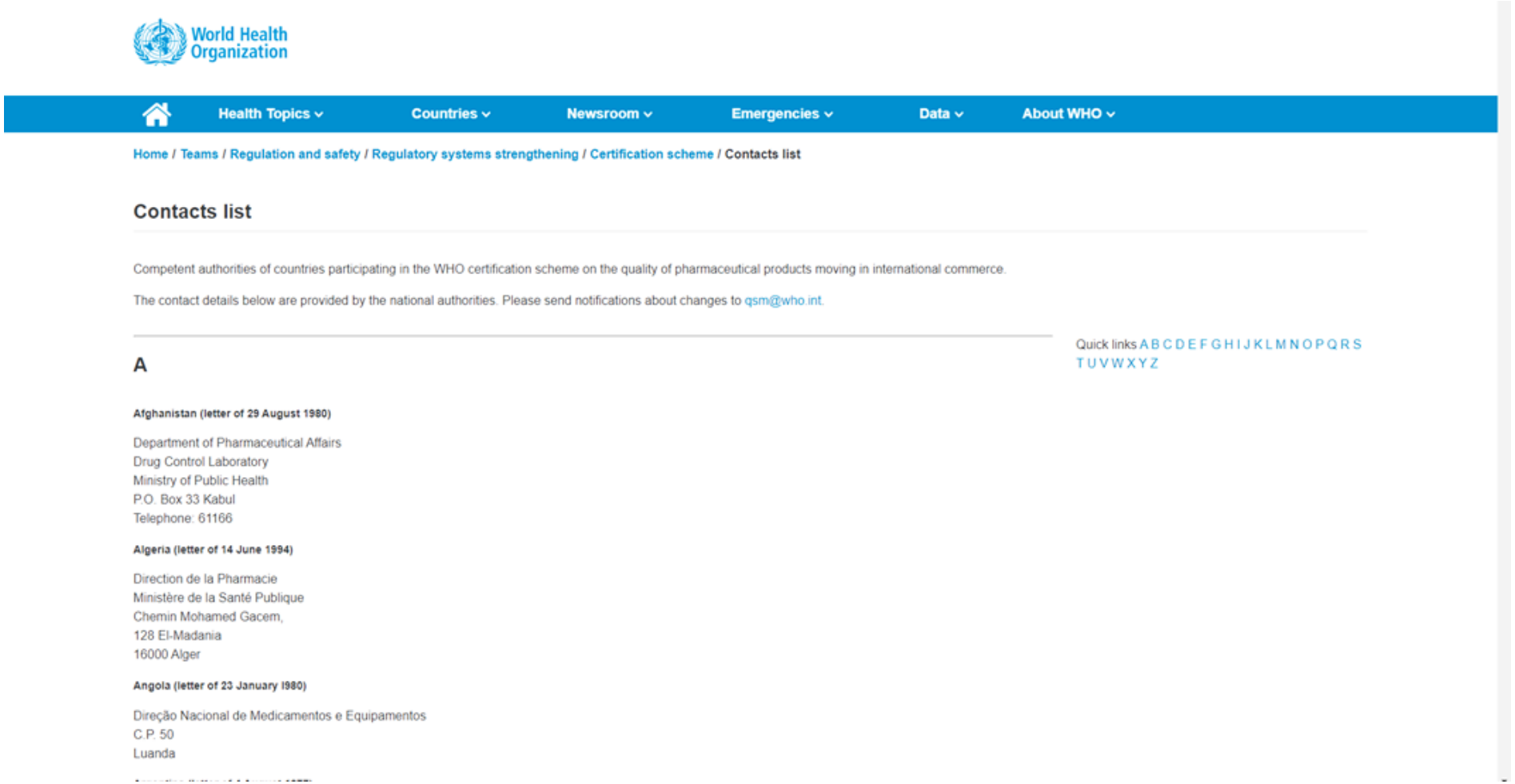
https://cliparts.zone

Any Member State can participate by notifying WHO its willingness to participate in the Scheme;

Each Member State assumes the responsibility to determine, through a process of self-evaluation, whether it satisfies the prerequisites to participate;

The Scheme contains no provision, under any circumstance, for external inspection or assessment.

Competent authorities in the WHO Scheme: 150 WHO Member States + European Medicines Agency



World Health Organization

Health Topics | Countries | Newsroom | Emergencies | Data | About WHO

Home / Teams / Regulation and safety / Regulatory systems strengthening / Certification scheme / Contacts list

Contacts list

Competent authorities of countries participating in the WHO certification scheme on the quality of pharmaceutical products moving in international commerce.

The contact details below are provided by the national authorities. Please send notifications about changes to qsm@who.int.

Quick links A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

A

Afghanistan (letter of 29 August 1980)

Department of Pharmaceutical Affairs
Drug Control Laboratory
Ministry of Public Health
P.O. Box 33 Kabul
Telephone: 61166

Algeria (letter of 14 June 1994)

Direction de la Pharmacie
Ministère de la Santé Publique
Chemin Mohamed Gacem,
128 El-Madania
16000 Alger

Angola (letter of 23 January 1980)

Direção Nacional de Medicamentos e Equipamentos
C.P. 50
Luanda

World Health Organization

Advantages and limitations of the Scheme

Advantages

- Standardised format defining information to be provided;
- Mechanism to improve interchange of information and to offer follow-up on complaints. (…when actually used).

Limitations

Certificate is as good as the certifying authority;

No mechanism to “screen” certifying authorities.

World Health Organization

1969 – 2022 context change

1969: few exporting countries; most importing countries had weak or no regulatory systems; many unscrupulous exporters were taking advantage of poor information and communication;

2022: many more exporting countries, communication is fast and information relatively easy to access, most NRA now asking the real thing: the dossier;

The application of the certification scheme becomes more and more challenging, and CPP has lost its original role.

Revised WHO Scheme: October 2020

Main changes of the revision included:

- Lead times of the certifying authorities can be very long: The certifying authority should establish a standard time frame, ideally within 20-30 working days;
- Importing countries require legalization of certificates, additional stamps, etc.: Legalization should not be requested;
- There are inconsistencies in the trade name of the product between the importing country and the certifying country: The model template of CPPs should be revised so that a proposed trade name in the importing country can be stated;
- "Statement of marketing authorization" (previously Appendix 2 of the Scheme) may not be used anymore: "Statement of marketing authorization" (Appendix 2) should be removed to simplify the Scheme if it has not been used anymore.

https://www.betterup.com/blog/networking

Good regulatory practice in 2022

- It is not possible that all countries build a regulatory system that is capable to perform all regulatory functions at the highest possible level of competence and effectiveness;

- NRAs need networking and reliance to eliminate duplication of work and liberate resources to focus on what must be done locally: e.g., assist manufacturers to achieve and maintain GMP compliance, control importation and domestic distribution, pharmacovigilance, and product information.

Good regulatory practice in 2022

Weak NRA

- works in isolation, duplicative work, contradictory outcomes with no benefit for public health, non-optimal use of resources;
- higher probability of substandard products and limited credibility within the health system.

Strong NRA

- networked with other NRAs, learning from each other, focusing on necessary tasks;
- less substandard products on the market and higher credibility of the system.

World Health Organization

Good regulatory practices and WHO Listed Authorities (WLA)

WLA is:

- strong NRA;
- effectively networked;
- investing in regional international collaboration.

World Health Organization

Impact of COVID-19 pandemic on regulatory processes

- 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 WHO Certification scheme**;
- Instead, and in order to maintain this critical service, they will use a **secure e-signature process**;
- WHO agrees with this initiative, which does not contradict the current WHO Guideline. **WHO recommends other regulators issuing Certificates to consider this approach too**;
- NRAs receiving Certificates are urged by WHO to accept the electronic signature. **This would be an example of regulatory flexibility in response to the COVID-19 pandemic.**

World Health Organization

Way forward for revision and improvement of the Scheme

- TRS1033: proposal for discussion, not yet submitted to World Health Assembly (WHA) for endorsement, not for implementation;
- Establishment of a Working Group to lead the process of revision and finalization of the Scheme based on the feedback from Member States;
- The aim is to submit for final endorsement by the WHA in May 2024;
- Plan for revision of the Scheme includes survey - to verify the contact details of national competent authorities participating in the Scheme.

www.who.int/medicines

- **Thank you for your attention!**

EMA’s practices and policies for issuing eCPP

Alberto Ganan Jimenez
Head of Procedures Office, Committees and Quality Assurance Department, European Medicines Agency

IFPMA efpia PhRMA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA's practices & policies for issuing CPP/eCPP

Webinar on New procedures and policies for the electronic Certificate of Pharmaceutical Product (eCPP)
EFPIA- FIFARMA 4th April 2022

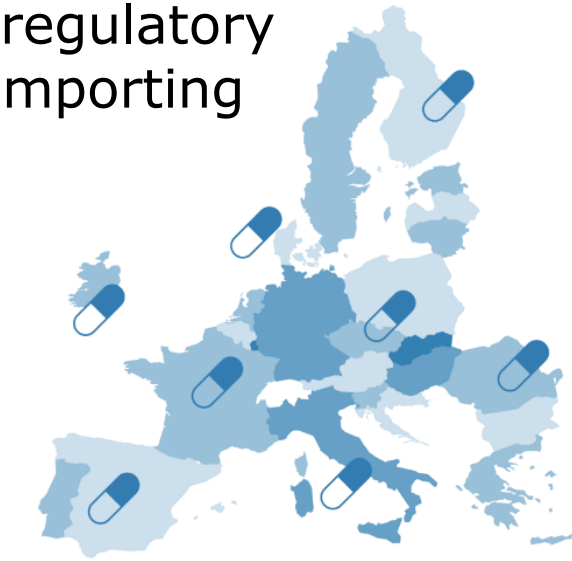
Alberto Ganan Jimenez, PhD
Head of Committees and Quality assurance Department *ad int.*
European Medicines Agency (EMA)

We live in a digital world

Digital transformation is a key priority area in the European Union and the European Medicines Agency.

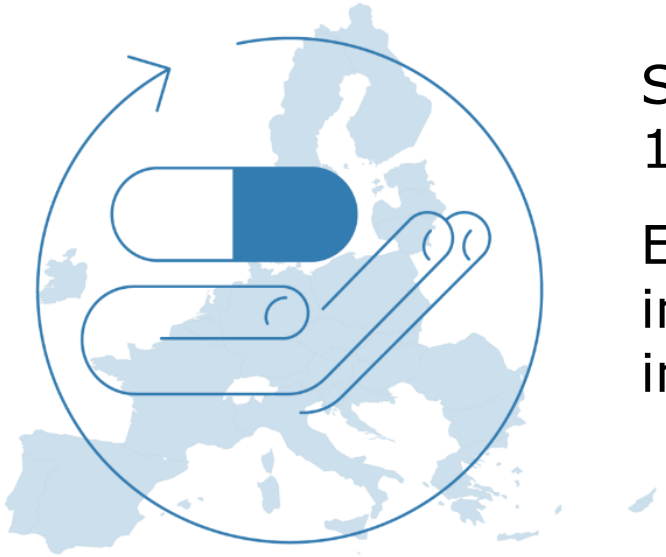
The electronic certificate (eCPP) is part of the EMA drive for digital transformation, **increase efficiency** and **going green** (reduction of paper usage and waste).

From March 2020, **EMA only issues 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 supported this initiative, recommended other regulators issuing certificates to consider this approach too and urged Authorities receiving Certificates to accept the electronic signature.

EMA eCPPs widely accepted worldwide



Since March 2020, EMA has issued more than 31,000 eCPPs from 13,000 requests issued for 136 importing authorities.

EMA eCPPs are **widely accepted** by the regulatory authorities of importing countries. EMA is not aware of any eCPP refused in any importing country.

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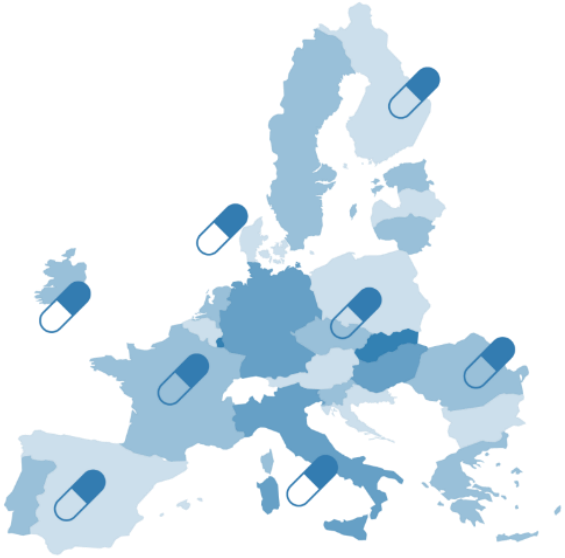
Some authorities still expect paper copies after the pandemia. **EMA does not issue paper CPPs anymore**.

EMA encourages importing countries to adapt their systems and legislation for accepting EMA eCPPs. Other authorities already issue or are considering to issue eCPPs.



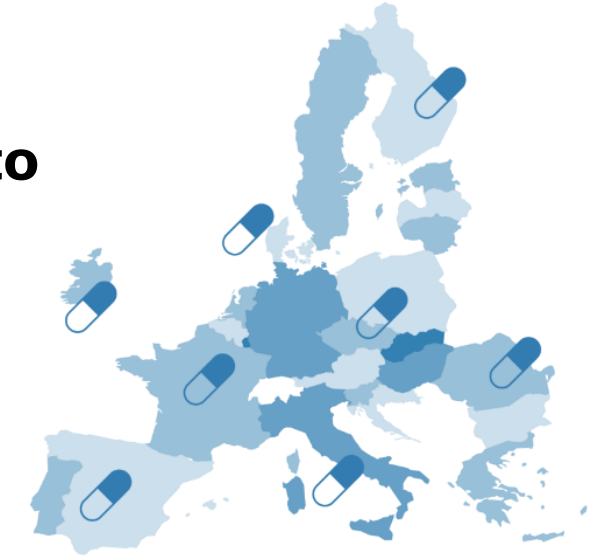
EU CPPs follow WHO Certification Scheme

CPPs issued by EMA of by EU National Regulatory Authorities are based on the **WHO Certification Scheme.**

EU CPPs contain the information recommended by WHO that is **accepted** by the authorities participating in the Scheme and is **comprehensive to assure the quality of a medicinal product**, its manufacture and control.

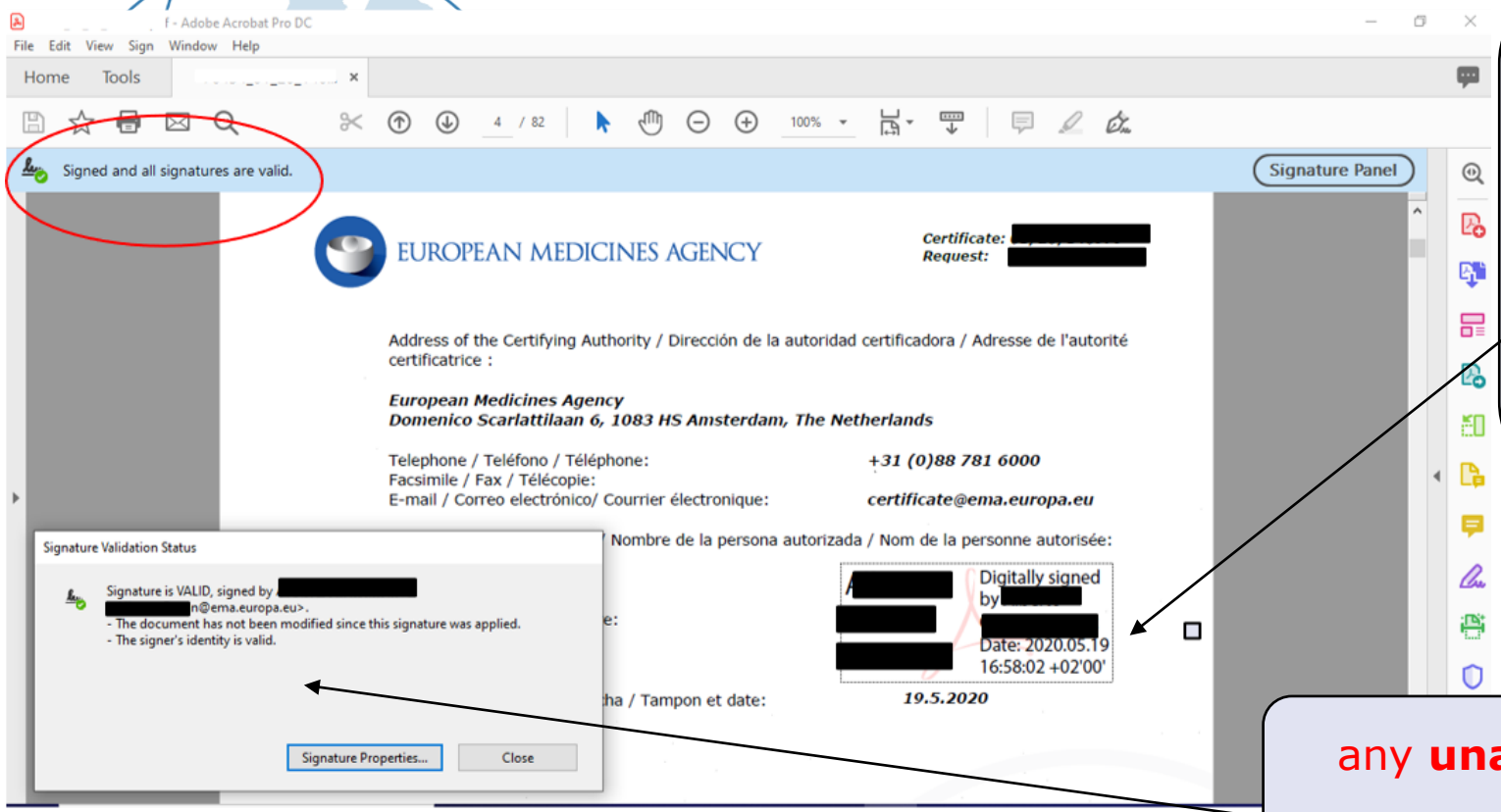
EU CPPs assure the quality of the medicines **without the need to provide additional information**.

eCPPs follow the same layout and contain the **same information** as previous EMA printed certificates as detailed in EMA guidance on Information Package.

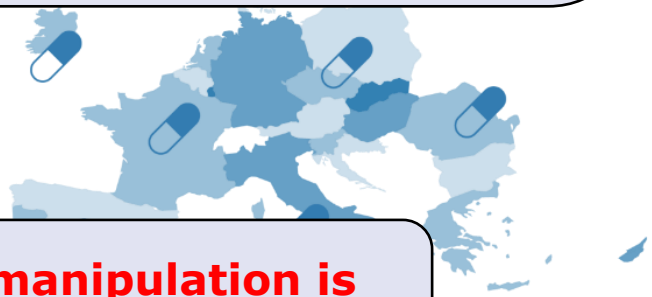


Electronic signature ensures the full integrity of eCPPs

eCPP is a PDF document containing an electronic signature ensuring that any manipulation can be detected.



Advanced electronic signature
- valid for legal documents
-complies with EU regulation (eIDAS)
- signature is uniquely linked to the signatory;
-created under his sole control;



any **unauthorised manipulation is detectable**

Authenticity check by EMA online verification system

Authorities of importing countries can confirm the authenticity and the details of an eCPP issued on [EMA website](#).

EUROPEAN MEDICINES AGENCY

Certificate: 01/20/140979
Request: 76434

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)

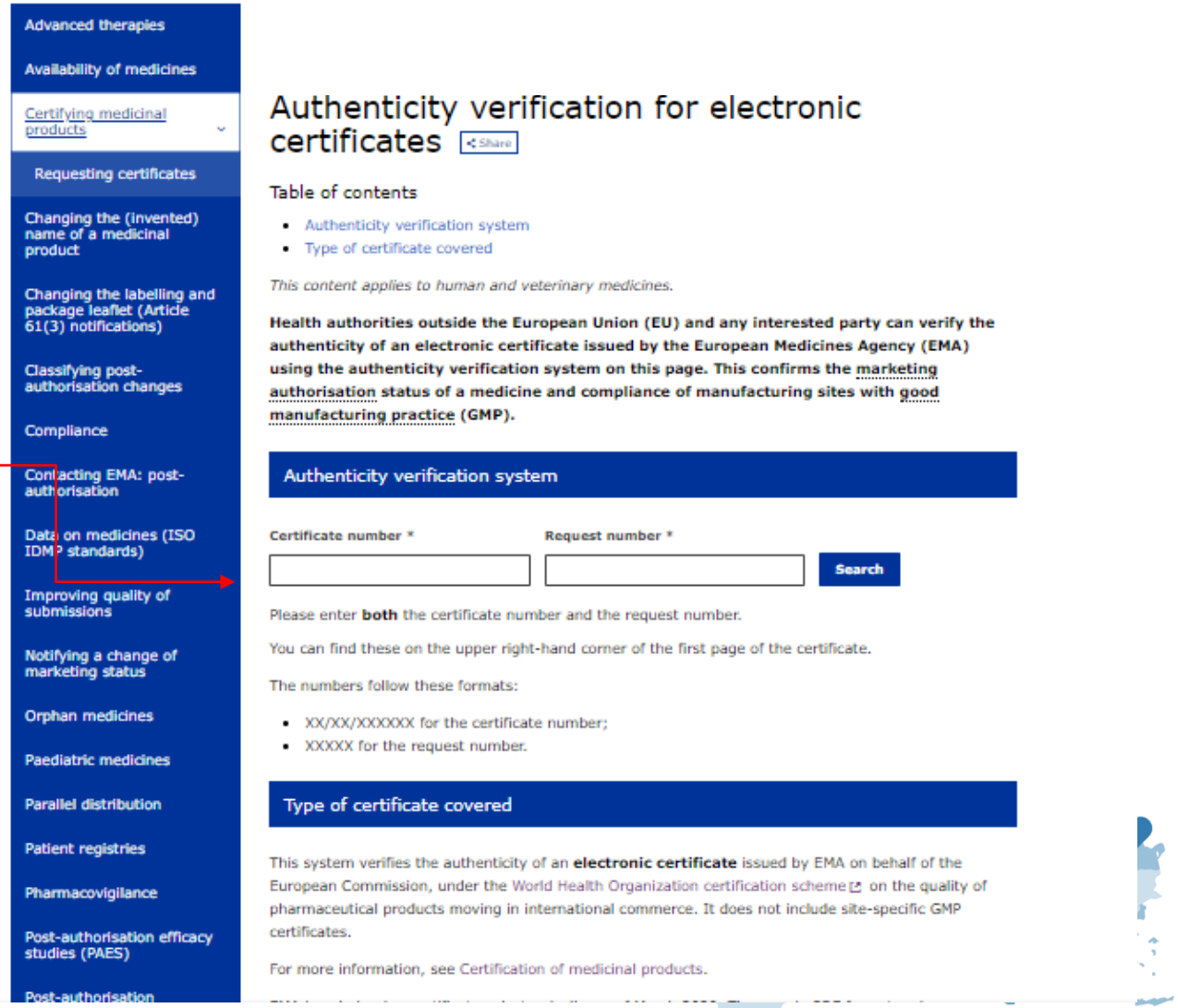
No. of Certificate / N° de certificado / N° du certificat: ***01/20/140979***

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.

Bélgica, Bulgaria, Chequia, Dinamarca, Alemania, Estonia, Irlanda, Grecia, España, Francia, Croatie, Italia, Chipre, Letonia, Lituania, Luxemburgo, Hungría, Malta, Países Bajos, Austria, Polonia, Portugal, Rumanía, Eslovenia, Eslovaquia, Finlandia, Suecia y Reino Unido.

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



Advanced therapies
Availability of medicines
Certifying medicinal products
Requesting certificates
Changing the (invented) name of a medicinal product
Changing the labelling and package leaflet (Article 61(3) notifications)
Classifying post-authorisation changes
Compliance
Contacting EMA: post-authorisation
Data on medicines (ISO IDMP standards)
Improving quality of submissions
Notifying a change of marketing status
Orphan medicines
Paediatric medicines
Parallel distribution
Patient registries
Pharmacovigilance
Post-authorisation efficacy studies (PAES)
Post-authorisation

Authenticity verification for electronic certificates

Table of contents

- Authenticity verification system
- Type of certificate covered

This content applies to human and veterinary medicines.

Health authorities outside the European Union (EU) and any interested party can verify the authenticity of an electronic certificate issued by the European Medicines Agency (EMA) using the authenticity verification system on this page. This confirms the marketing authorisation status of a medicine and compliance of manufacturing sites with good manufacturing practice (GMP).

Authenticity verification system

Certificate number * | Request number * | Search

Please enter **both** the certificate number and the request number.

You can find these on the upper right-hand corner of the first page of the certificate.

The numbers follow these formats:

- XX/XX/XXXXXX for the certificate number;
- XXXXX for the request number.

Type of certificate covered

This system verifies the authenticity of an **electronic certificate** issued by EMA on behalf of the European Commission, under the World Health Organization certification scheme on the quality of pharmaceutical products moving in international commerce. It does not include site-specific GMP certificates.

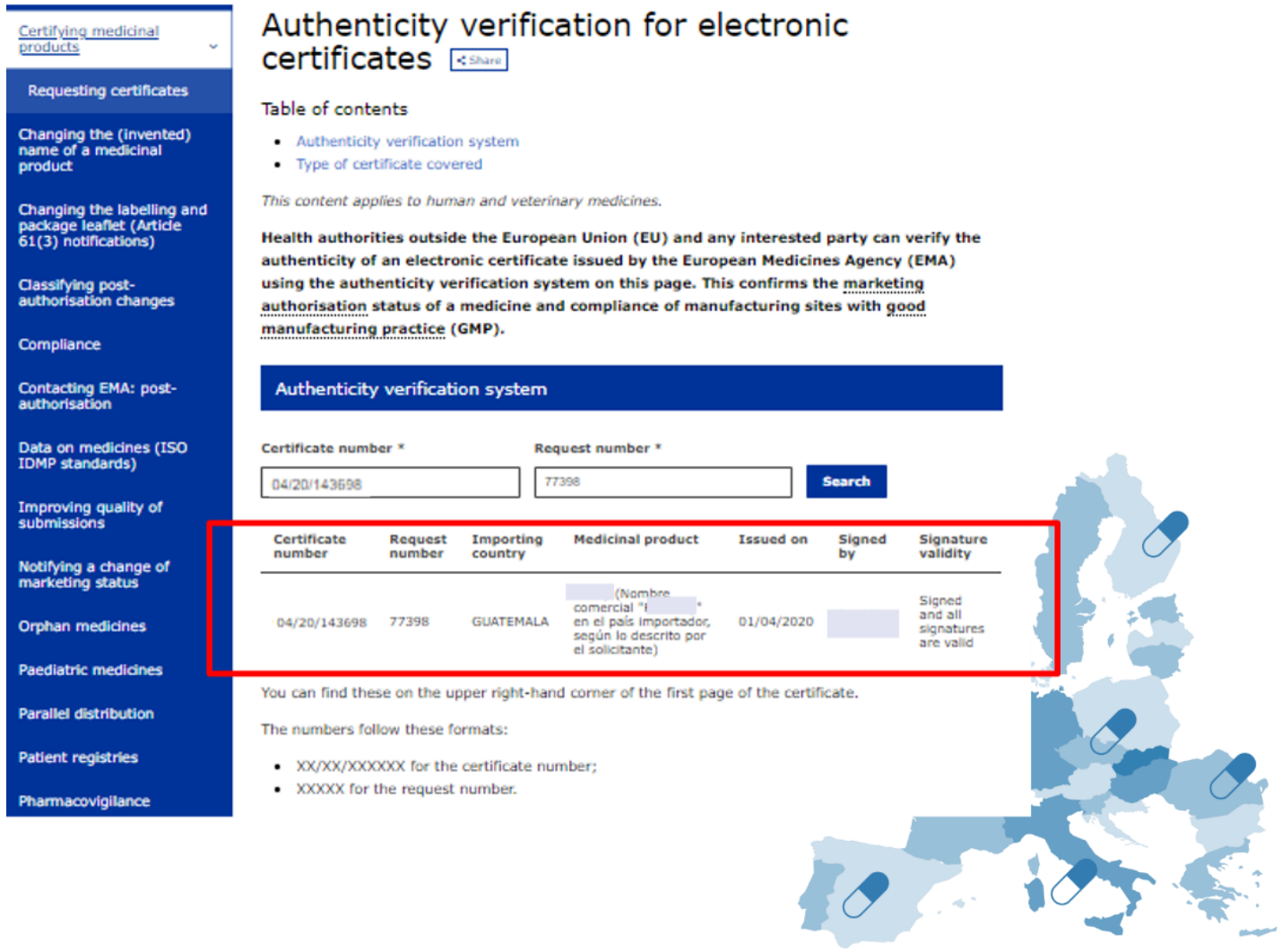
For more information, see Certification of medicinal products.

Authenticity check by EMA online verification system

Upon inclusion of the unique certificate and request numbers, the tool displays the following eCPP details: importing country, medicinal product/pharmaceutical form, date, signatory and confirmation of validity.

These details are **sufficient to verify that the eCPP has been issued by EMA.**

This information is available **from the next day following the issue of the** eCPP by EMA.

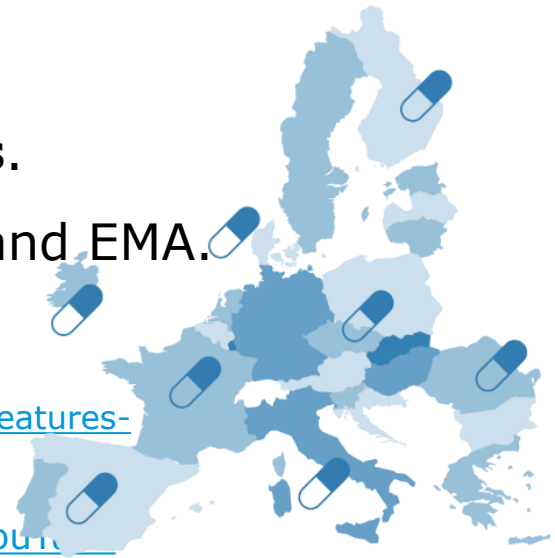


eCPP integrity and authenticity is guaranteed without the need for any additional legalisation

An importing authority can have **full assurance of the integrity and authenticity** of the eCPP based on the **electronic signature** and EMA **online verification tool.** This is explained in the **Information note*** published on EMA website and in the YouTube video.

Some importing countries still require **further legalisation of CPPs/eCPPs**.

This requirement is considered **unnecessary and not supported** by WHO and EMA.



*https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/information-note-format-validity-features-electronic-certificates-medicines-issued-european_en.pdf

How to check the authenticity of electronic certificates issued by the European Medicines Agency - YouTube

Contact EMA certificates team

Authorities from importing countries, Marketing Authorisation Holders or any interested party can contact EMA Certificates team by **sending an email** to certificate@ema.europa.eu

Until the launch of the online verification tool, this email address was used to confirm the authenticity of eCPPs via email. EMA replied to these requests within 2 days.

This email address can be still used **for any query related to certificates issued by EMA**. Any importing authority that has any concern in accepting electronic certificate can contact EMA directly through this email address.

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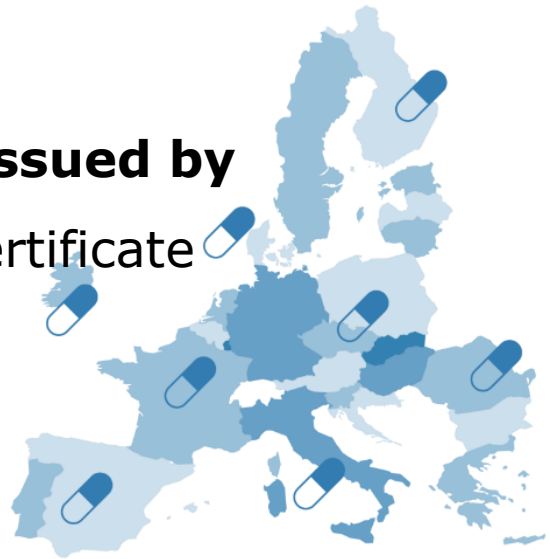
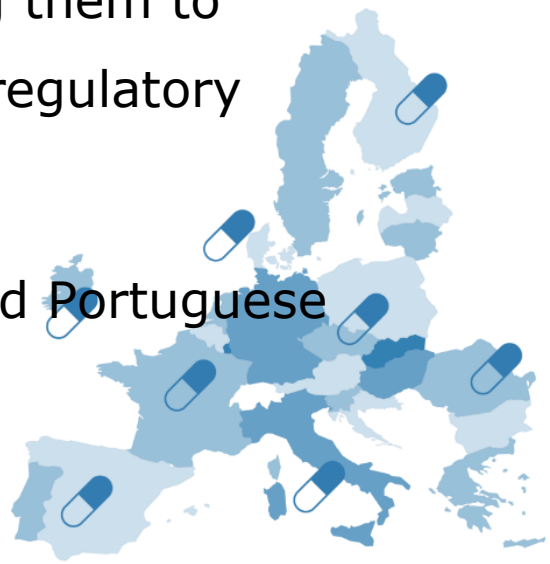


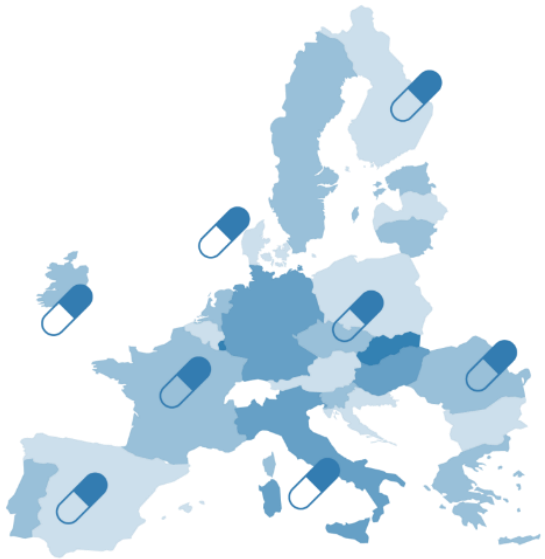
EMA supports a worldwide implementation of eCPPs

- **International collaboration with WHO**. WHO supported the initiative and confirmed its compatibility with WHO Certification Cheme.
- EMA **shared experience to interested issuing authories** that have approached EMA and are considering the implementation of eCPPs.
- EMA sent **letters to ~70 receiving authorities** urging them to **implement the necessary changes** to their national regulatory systems.
- EMA has provided letters in English, Spanish, French and Portuguese explaining



Final remarks

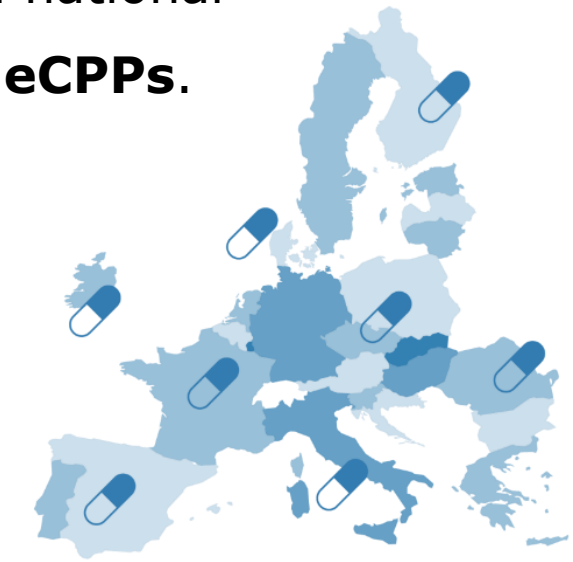
- **eCPPs** is the permanent and only format for issuing CPPs by EMA. EMA does not issue printed certificates anymore.
- The **electronic signature** and safety features fully assure the **integrity** of certificates issued by EMA
- The **online verification tool** on EMA website confirms the **valididty** and **authenticity** of the eCPPs issued by EMA.



Final remarks

- **Further legalisation of CPPs/eCPPs** is considered **unnecessary** and **not supported** by WHO and EMA.

- EMA urges receiving authorities to **undertake the necessary revision of legislation or technical changes** in national regulatory systems **for the full acceptability of eCPPs**.



Thanks for your attention

certificate@ema.europa.eu

EMA certificates webpage (link)

EMA eCPP verification tool (link)

YouTube video explaining eCPPs and verification tool (link)

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

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EDA's lessons from the use of eCPPs

Maryam Ali Abdelmoneim
Box Inquiry Unit Manager in Administration of Registration, Egyptian Drug Authority

IFPMA efpia PhRMA

EGYPTIAN DRUG AUTHORITY

EDA

هيئة الدواء المصرية

Bio-Inn

CA of Biological & Innovative Products and Clinical Studies

الإدارة المركزية للمستحضرات الحيوية والمبتكرة والدراسات الإكلينيكية

CPD

CENTER FOR CONTINUING PROFESSIONAL DEVELOPMENT

مركز التطوير المهني المستمر

CPPs & e-CPPs in EDA

Ph/ Maryam Ali
B.Sc. pharmacy
Registration administration

Index

The importance of CPP in the context of approval of medicines in Egypt

- **According to the regulations in Egyptian Drug Authority, CPP is a mandatory document for the Registration of any imported Product.**
- **It summarizes all relevant data regarding the product.**
- **The presence of CPP ensures the following:**

1- The regulatory authority approval was based on a full evaluation of the product's Quality, Safety & Efficacy.

2- The product is marketed in the CPP-issuing country which is mandatory for products submitted for registration in Egypt.

3- The product is manufactured under GMP conditions.

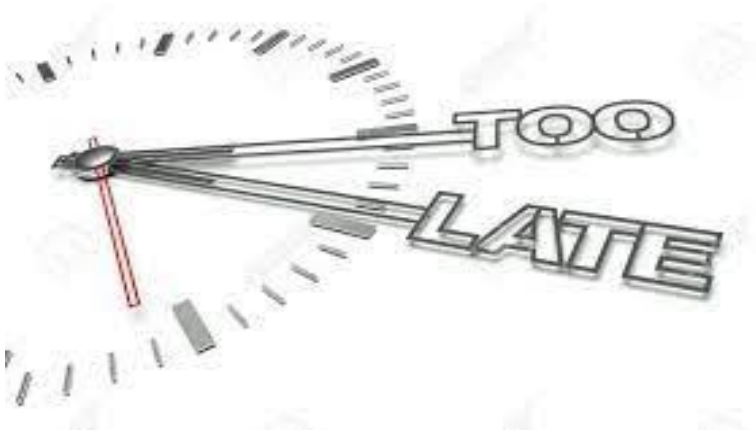
4- It reflects all approved manufacturers of the product, concentration & presentation .

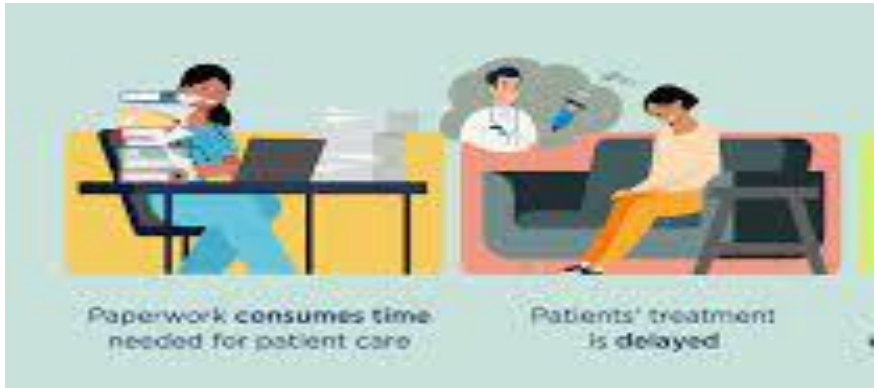
The importance of CPP in the context of approval of medicines in Egypt cont.

- It is required for new product submissions, certain variations, renewals.
- It should be submitted at beginning of the review.

Factors triggered e-CPP implementation and acceptance/ acknowledgment in EDA:

- During the COVID-19 pandemic and due to lockdown many Authorities started to issue CPP with electronic signatures in order to maintain this critical service.
- The legalization process takes more and more time as the embassies didn't work with full capacity.
- The processing time for CPPs could range from a few weeks to several months, depending upon the health authority.
- Legalization adds more time which has a great impact on CPP availability.
- Ultimately patients' access to new medicines is the real impact of this delay.





Factors triggered e-CPP implementation and acceptance/ acknowledgment in EDA Cont.

- The pandemic introduced challenges for regulators and for the industry because it forced all processes to be digitalized.
- In March 2020, the European Medicines Agency (EMA) announced that it would no longer provide printed Certificates of Pharmaceutical Products (CPP) but only electronically signed and authenticated ones, that would enable EMA to continue to be able provide certificates during the COVID-19 pandemic. The Agency considers electronic CPPs as the permanent way of issuing certificates.
- WHO agrees with this initiative, which does not contradict the current WHO Guideline. WHO recommends other regulators issuing Certificates consider this approach too.
- Health authorities like EMA, FDA afford different verification systems (through their official websites) to verify the authenticity of the certification from the issuing authority itself.

Factors triggered e-CPP implementation and acceptance/ acknowledgment in EDA Cont.:

- As legalization is not part of the WHO Scheme.
- Official governmental authority of the certifying country signs the CPP So Legalization does not add value to the CPP, as it confirms only the signatures on the CPP but does not confirm any details of the CPP content.
- Accordingly EDA decided to update the regulations which request original legalized CPP and transfer to e-CPP as long as its authenticity can be checked from issuing authority itself.


تعديل بعض الشروط الخاصة بالمستندات
اللازم تقديمها للمستحضرات المستوردة
تامة الصنع بالخارج او مصنعة بالخارج
ومغلفة محليا او مصنعة بترخيص من شركة
اجنبية

٢٦ يوليو ٢٠٢٢

بناءً على موافقة رئيس هيئة الدواء المصرية على تعديل بعض الشروط الخاصة بالمستندات اللازم تقديمها للمستحضرات المستوردة تامة الصنع بالخارج او مصنعة بالخارج ومغلفة محليا او مصنعة بترخيص من شركة اجنبية، تعلن الإدارة المركزية للمستحضرات الحيوية والمبتكرة والدراسات الإكلينيكية على الموافقة على استقبال:

"(Electronic certificate of pharmaceutical product (eCPP"

بدون الحاجة الى توثيقها من السفارة المصرية بالخارج ما دامت تتوفر وسيلة للتأكد من صحة البيانات الواردة إما عن طريق البريد الإلكتروني، او الروابط المعلنة من الجهة المصدرة لتلك الشهادات

اشعارات

المستندات الخاصة بالمستحضرات تامة الصنع بالخارج

الإدارة المركزية للمستحضرات الحيوية والمبتكرة

هيئة الدواء المصرية

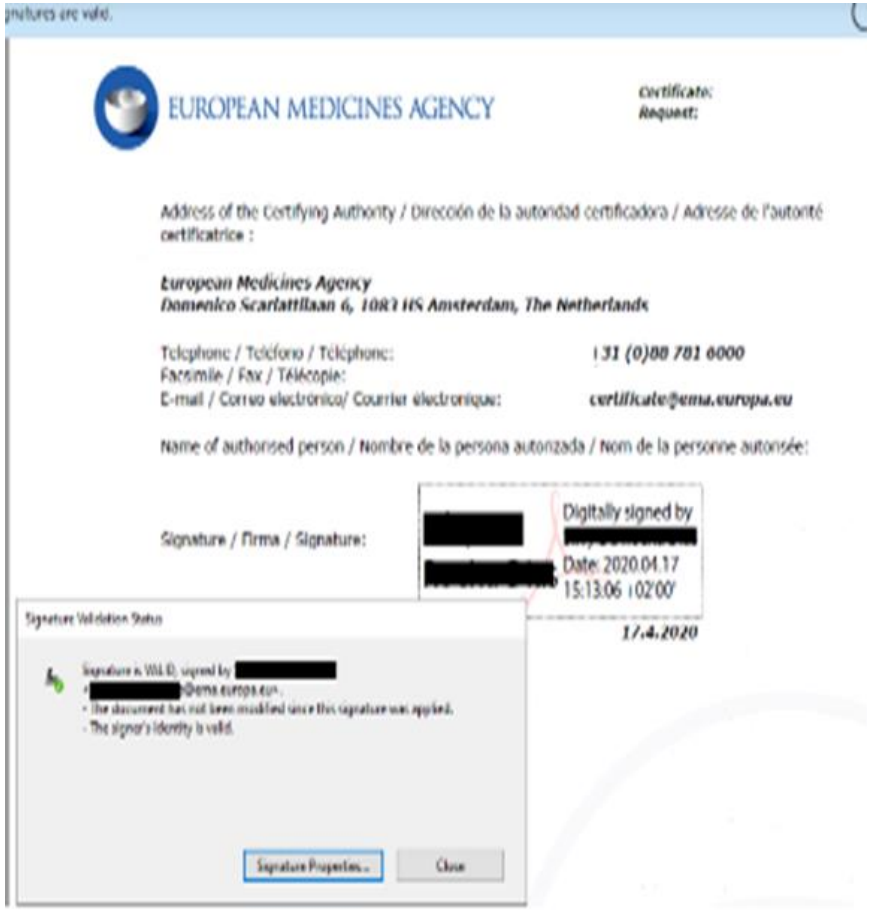
Outcome of using e-CPP

- **Allow continuous availability of CPP during Covid-19 pandemic.**

- **The change from paper to electronic certificates will improve efficiency in issuing CPPs, reducing the amount of time it takes to issue and legalize CPP and reduce time for submission of registration dossier.**
- **Allow Faster access of new medicines to patient.**

Outcome of using e-CPP cont.

- Allow quicker and easier verification from issuing authority itself.
- Some Authorities will offer advanced electronic signature which is linked to the data signed therewith in such a way that any subsequent change in the data will be detectable.
- Reduce paper submitted which also improve work environment and matching with sustainability approaches digitalization Era.



Recommendation to other Authorities

It is Recommended to all CPP requesting authorities to accept Electronic CPP without need to paper legalized one as long as there is a verification system from issuing authority itself .

Thank you

EGYPTIAN DRUG AUTHORITY

EDA

هيئة الدواء المصرية

Bio-Inn

CA of Biological & Innovative Products and Clinical Studies

الإدارة المركزية للمستحضرات الحيوية والمبتكرة والدراسات الإكلينيكية

CPD

CENTER FOR CONTINUING PROFESSIONAL DEVELOPMENT

مركز التطوير المهني المستمر

Q&A panel discussion with regulators and audience

Please submit your questions in the Q&A box. If possible, include your name and organization.

Veuillez soumettre vos questions dans l’espace Q&A. Si possible, veuillez inclure votre nom et organisation.

Envíe sus preguntas en el cuadro de preguntas y respuestas. Si es posible, incluya su nombre y organización.

Por favor, envie suas perguntas na caixa de perguntas e respostas. Se possível, inclua seu nome e organização.

All presentations will be circulated to registered participants after the webinar

IFPMA efpia PhRMA

KEY TAKEAWAYS

Conclusion
Conclusión
Conclusão

THANK YOU

Merci

Muchas Gracias

Muito Obrigado

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