Working Group:
CFG & FSC – Apostille

14-NOV-2024

INTER-AMERICAN COALITION FOR
REGULATORY
CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

CFG & FSC – Apostille.

Strategies to simplify and eliminate the requirement

One standard, one test, accepted everywhere for any medical technology scope

– EXECUTIVE COMMITTEE

Main Objective

Develop strategies to work with LATAM regulators to:

- ***Accept electronic CFG/FSC (document and apostille);***
- **Remove the requirements (when possible);**

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ROADMAP

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WG Survey

Outputs:

- Every WG member must know the IACRC position paper and MOH requests for Latam countries regarding this topic.

- Leverage position papers already build by local trade associations.

Data analysis

Outputs:

- Define action plan and timelines,
- Define extra support required to achieve results.

Schedule & Responsible

Outputs:

- Schedule of required activities and assign responsibilities across WG.

WG meetings

Outputs:

- Discuss and follow up /monitoring milestones and advances

Deliverables

Outputs:

-Document/position to recommend the influence according to each country regulator maturity level / regulations.

- Trade Associations and Gov Affairs influencing MOH and other authorities.

IACRC Positioning on
Certificates of Free Sale (CFS) / Certificates to Foreign Government

- Certificates of Free Sale (CFS) / Certificates to Foreign Government (CFG), initially established in the 1970's, were measures to enable and promote international regulatory and trade certainty – in particular as a type of authentication of documentation, but after years of global cooperation, modern paperless trade and regulatory tools and mechanisms are available that can be used to ensure proper regulatory and trade oversight between governments.
- The information provided in CFS/CFGs is now available and assessable in many jurisdictions any day and time via trusted sources from government authorities or multilateral organizations such as the US FDA, EU Commission, World Health Organization (WHO) websites or digital databases

IACRC Positioning on Certificates of Free Sale (CFS) / Certificates to Foreign Government

- Certificate issued by FDA after 2 January 2024 are electronically;
- Many countries in Latin America require a Certificate of Free Sale / Certificate to Foreign Government for imported medical devices;
- Some countries also requires Apostille / legalization and sworn translations of these documents;

Transitioning import and export control documentation into electronic processes is a **core aspect of medical device regulatory convergence** and reducing unnecessary costs to patient access.

Apostille: traditional mechanism to provide an increased level of confidence that the document is authentic and not a forgery. Formally, the Hague Convention of 5 October 1961 "Abolishing the Requirement of Legalization for Foreign Public Documents" (the "Apostille Convention") provides the international legal framework governing Apostilles. Countries that are not members of the Apostille Convention cannot ask for an Apostille and must follow the traditional path for legalization of documents.
The electronic Apostille Program (e-APP) was launched in 2006 to promote and assist in the implementation of technology under the Apostille Convention. An e-Apostille is an Apostille issued in electronic form and signed by electronic signature with a digital certificate.

Traditional Legalization Process: procedures whereby the signature / seal / stamp on a public document is certified as authentic by a series of public officials along a "chain" to a point where the ultimate authentication is readily recognized by an official of the State of destination and can be given legal effect there. As a practical matter, Embassies and Consulates of the State of destination located in (or accredited to) the State of origin are ideally situated to facilitate this process.

Sworn translation is a certified translation carried out by a sworn translator (also referred to as Official Public Translator and Commercial Interpreter). It is officially recognized by institutions and public authorities and is regarded as an official document.

Where we are today

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APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Land/Pays/Land	***BELGIË - BELGIQUE - BELGIEN***
2. Deze openbare akte is ondertekend door : Le présent acte a été signé par : Diese öffentliche Urkunde ist unterschrieben von :	***De Cuyper, Xavier***
3. Handelend in hoedanigheid van : Agissant en qualité de : In seiner/ihrer Eigenschaft als :	***Gedelegeerde ambtenaar/Fonctionnaire délégué/Beauftragter Beamter***
4. Is voorzien van het zegel van : Est revêtu du sceau de : Sie ist versehen mit dem Siegel des/der :	***FOD Volksgezondheid , Veiligheid van de Voedselketen en Leefmilieu/SPF Santé Publique, Sécurité de la Chaine alimentaire et Environnement/FÖD Volksgesundheit, Sicherheit der Nahrungsmittelkette und Umwelt***

Voor echt verklaard / Attesté / Bestätigt

5. ***Te Brussel/A Bruxelles/In Brüssel***	6. Op/Le/Am : ***08-10-18***

7. Door FOD Buitenlandse Zaken, Buitenlandse Handel en Ontwikkelingssamenwerking
Par le SPF Affaires étrangères, Commerce extérieur et Coopération au Développement
Durch FÖD Auswärtige Angelegenheiten, Außenhandel und Entwicklungszusammenarbeit

8. Onder Nr./Sous le n°/Unter Nr. : ***181099584965***

9. Stempel/Sceau/Stempel:

10. Ondertekening/Signature/Unterschrift:

Digitally signed by
FPS Foreign Affairs
Belgium

Prijs/Prix/Preis: ***20*** EUR

Deze Apostille waarborgt de authenticiteit van de inhoud van het document niet.
Cette Apostille ne garantit pas l'authenticité du contenu du document.
Diese Apostille dient nicht dem Beweis des Authentizität des Inhalts des Dokuments.

Ongeldige elektronische handtekening?	Deze Apostille controleren?
Signature électronique invalide?	Vérifier cette Apostille?
Ungültige elektronische Unterschrift?	Diese Apostille überprüfen?
elegalisation.diplomatie.be/help	legalweb.diplomatie.be

Your FSC/CFG buddies

Map the impact per country of the e-CFG issued by FDA on Jan/2024	• Informal approach to regulators to understand if they received this information. • How will it impact regular process?
Trade Associations	• Verify if local trade associations have already evaluated this topic; • Understand Coalition position paper and use it to start conversations with MoHs. • **Refined survey to better understand the real impact**
Legal opinion regarding country regulations related to apostille documents	• Work on the questions to be addressed by legal to have success on this assessment. • Understand requirements of each country.
Define how to influence small countries to accept electronic documentation	• Create a **macro** and personalized strategy according to each country regulation maturity level. • ***Provide training to Regulators.***
Define countries that would be open to remove the need of a CFG/ FCS	• When possible, work with Government affairs to do a political influence to support this strategy.

Survey related to e-FSC/CFG

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1- Country;

2- Trade Association;

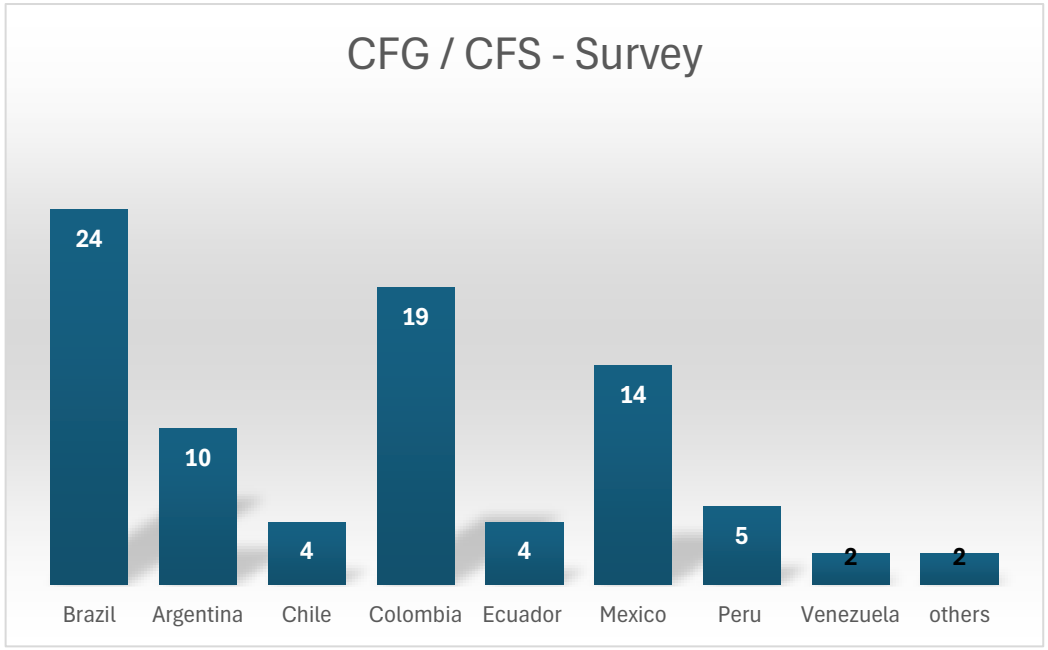
3- Do you know that starting in January, the FDA will no longer issue physical CFGs?

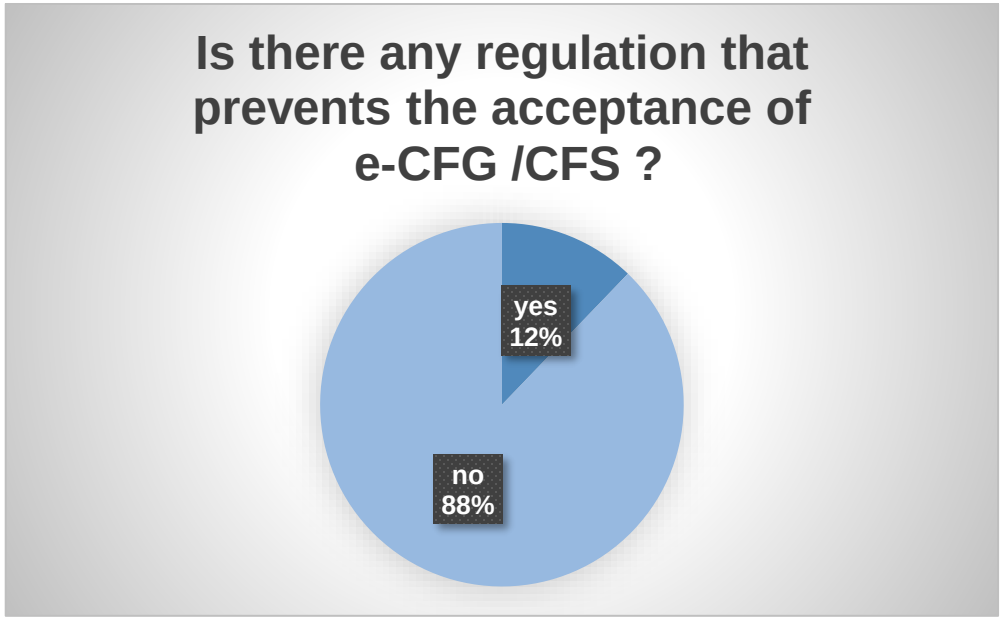
4- Is your country/ regulation ready for this change?

5- ***Can you receive the electronic CFG without printing it? Is that acceptable to you?***

6- ***Is there any regulation that prevent the acceptance of e-CFG and e-apostille?***
If yes, could you please include the regulation number:

IACRC Positioning on Certificates of Free Sale (CFS) / Certificates to Foreign Government





IACRC Positioning on Certificates of Free Sale (CFS) / Certificates to Foreign Government

Latam Countries that requires CFG/CFS legalized / apostilled:

Argentina	Guatemala
Bolivia	Honduras
Colombia	Mexico
Costa Rica	Nicaragua
Chile	Panama
Dominican Republic	Paraguay
Ecuador	Peru
El Salvador	Uruguay

Today and next steps…

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e-CFG/FSC (document and apostille) is accepted; ✓

- *Countries get used to electronic version / or printing locally*

WI for MDSAP countries was created ✓

- It was created a WI with steps on how to find the products approval in MDSAP countries website

Cover letter – draft ✓

- Cover letter draft was built to show the reasons Coalition is working on it

Document shared with ANVISA

- ANVISA will provide feedback on the document

Document will be shared with other regulators

- Coalition will start to share the document with local TA and regulators

IACRC Positioning on
Certificates of Free Sale (CFS) / Certificates to Foreign Government

Country	Requirements	Legal Reference	Legal text
Brazil	CFS + Apostille and sworn translation (for documents that are not in Portuguese, English or Spanish).	In vitro diagnostics products: RDC 36/2015 RDC 830/2023 Medical Device: *RDC 751/22 ANVISA*, article 14, IV: Art. 14	**In vitro diagnostics products do not require CFS.** ***Medical Devices Class I and II do not require CFS.*** ***Medical Device (Class II and IV): The applicant to apply for the registration of a medical device must proceed with the payment of the corresponding fee and submit the following documents to ANVISA:*** ***(IV) for imported medical devices: proof of registration or free trade certificate or equivalent document, granted by the competent authority of the country where the medical device is manufactured and marketed or only marketed, issued in a maximum of two years - when there is no express validity indicated on the document -, must be consularized or apostilled, and accompanied by a sworn translation when not written in Portuguese, English or Spanish.***

- Survey through TAs
- Define a strategy to influence small countries to accept electronic documentation.

- Share the document with a key regulator to ask feedback.
- Share WI and with local TA and Regulators
- **Map countries that would be open to remove the need of a CFG/ CFS**.

Q1-2024

Q2-2024

Q3-2024

Q4-2024

Q1-2025

- Analyze all available position papers;
- Understand the impact in an informal way;
- *Map the impact per country of the e-CFG issued by FDA on Jan/2023.*

Work in a document to support regulators to find approvals in their websites.

- **Map countries that would be open to remove the need of a CFG/ CFS**.
- Government Affairs support to work on country regulations.
- **Influence outcomes**

Use Coalition position paper to start conversations with MoH.
Use ANVISA as a benchmarking to all Latam countries

Renata Brandão

CFG & FSC – Apostille

Working Group

THANK YOU

SANDRA LIGIA GONZÁLEZ

Executive Secretary

STEVEN BIPES

Vice President, Global Strategy and Analysis, AdvaMed

LETICIA SEIXAS

Deputy Executive Secretary
Executive Secretary Brazil

ANDREW BLASI

Director, C&M International

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