Standards Alliance Phase 2 COVID-19 Medical Devices Regulatory Convergence (MDRC) Project

External Stakeholders Meeting

October, 2023

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Electronic CFG/FSC – A proactive approach to a new reality. Position paper on eCFG/eFSC

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Objectives

Part I - Provide clarifying definitions related to Certificates of Free Sale (CFS) / Certificates to Foreign Government (CFG) as they apply to MD/IVDs.

Part II - Present the recommendations of the Inter-American Coalition for Regulatory Convergence – Medical Technology Sector regarding modernization of MD regulatory frameworks that require CFS/CFGs.

Part III - Provide a summary of the main requirements and legal backgrounds of selected Latin American countries in relation to the presentation of CFS/CFGs.

CFS/CFG

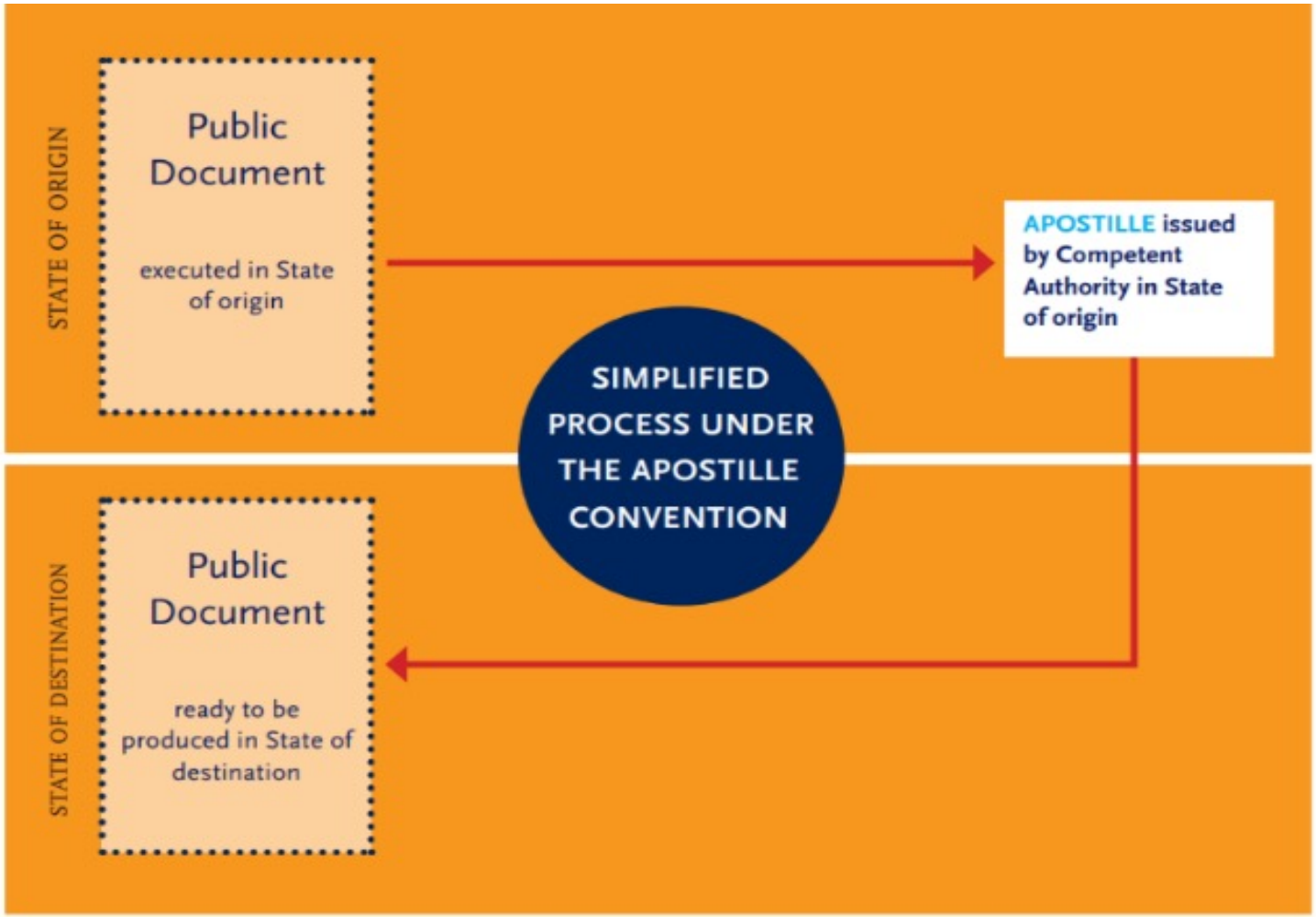
- The Certificate of Free Sale (CFS), the Free Sale Certificate (FSC), the Certificate to Foreign Government (CFG), the Certificate of Free Trade (CFT) and the Declaration of Free Sale (DFS) (hereafter referred to as “CFS/CFG”) are different nomenclatures for the same document.

a) attests that a product does not suffer any commercialization restriction in the market in which it was manufactured or marketed;

b) states that a product follows the regulations and technical norms of the country of origin and, thus, can enter the market of the importing country as condition of the importing country authorities; and

c) makes possible the registration of the product in the importing country, enabling the company to participate in bids and other events in the importing country.

Apostille (e-Apostille)



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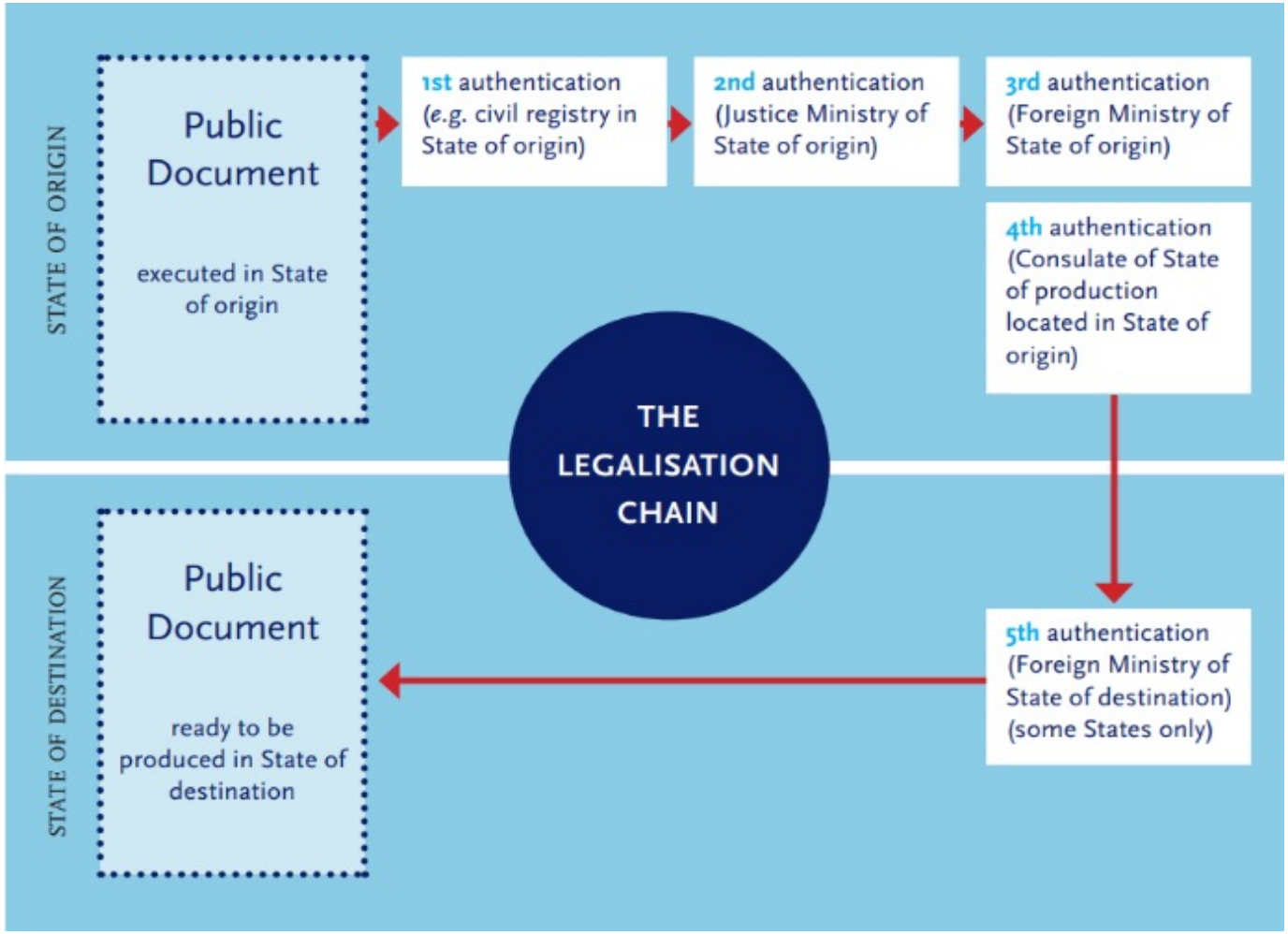
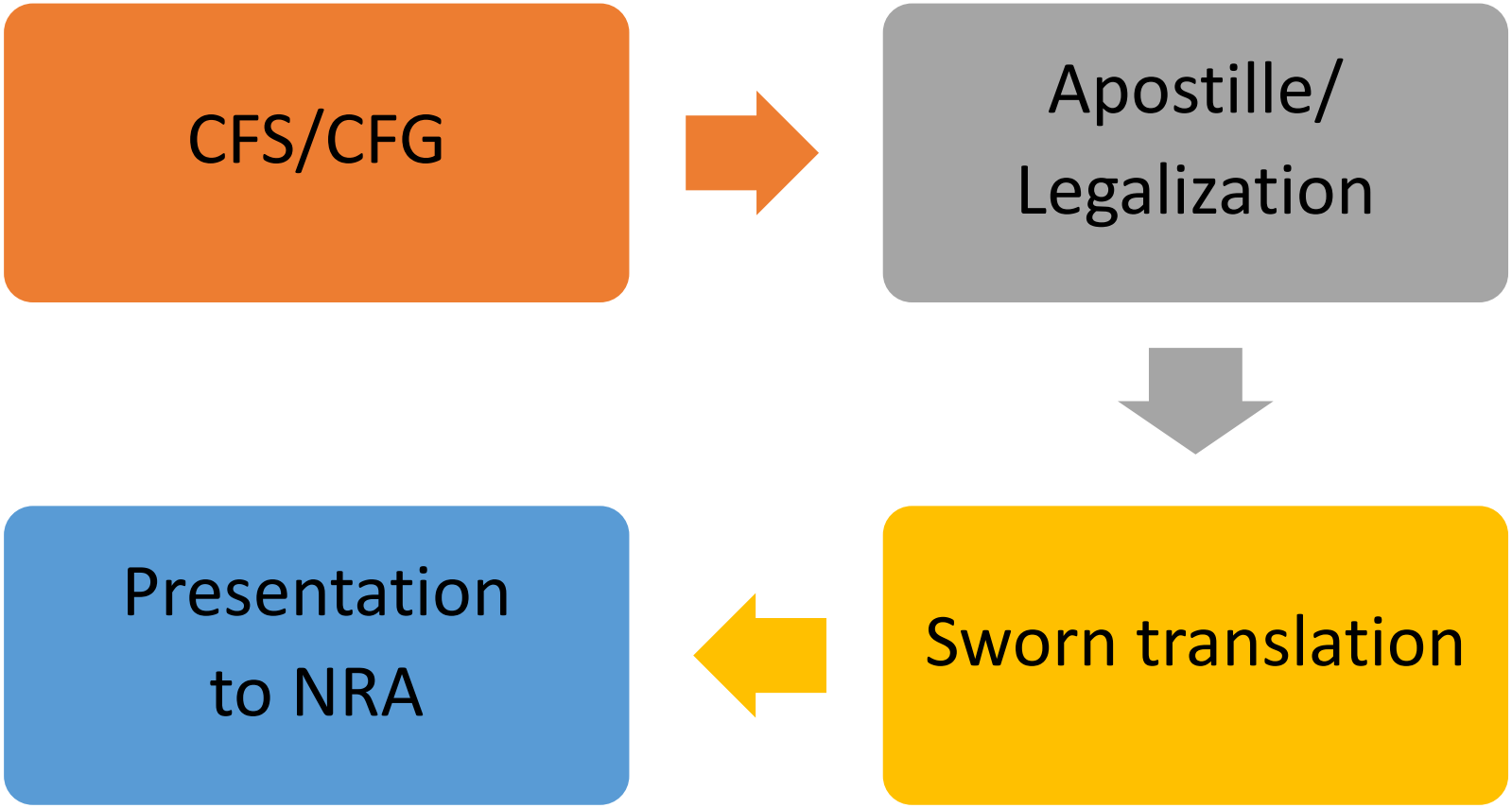
Traditional Legalization Process



Complete Process for Presentation CFS/CFG



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Key facts

i. There are many countries in the Americas which currently require a CFS/CFG for regulatory, customs and procurement purposes for imported MD.

ii. 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.

iii. Some countries require CFS/CFG to go through an additional validation process requiring an Apostille and/or legalization and sworn translations.

iv. Apostilles may only be issued by designated government bodies and sometimes it takes months to have an Apostille issued.

v. The U.S. Food and Drug Administration (FDA) is transitioning from paper export documents and all certificate request reviews will be issued electronically.

vi. These processes may not currently accept electronic documents and therefore, the lack of paper certificates is anticipated to potentially disrupt or prevent the registration, import and market authorization of MD/IVDs.

vii. Transitioning regulatory, customs and procurement control documentation into electronic processes is a core need to reduce costs and to improve patient access.

Key messages

1. Countries should make an effort to embed digitalization in the local regulations of MD.
2. Authorities should consider removing the requirement for a CFS/CFG if the MD/IVD is already approved by an internationally recognized regulatory agency/body and/or is already exported to selected countries that do not always require the CFS/CFG.
3. Countries should endeavor to accept the official electronic format of CFS/CFG, without the requirements of an Apostille or legalization.
4. Issuing CFG/CFSC and their subsequent legalization or Apostille process represent a critical supply chain bottleneck that impacts the availability of the health registrations necessary for the market authorization of medical devices into countries.
5. In case there is a need for translation of the official electronic CFS/CFG countries should commit to accept the sworn translation of the electronic document.
6. Countries should strive to implement paperless public policies, including electronic process, and the elimination of wet signatures.

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Final message

Countries should implement transitional measures so that submissions of electronic and paper legal documents are accepted under the conditions outlined.

This is crucial as the procedures required to enact definitive policy changes may depend on inter-ministerial requirements or new legislation, not solely on the medical device regulatory authority.

This will allow the gradual transition of technological advance and, updated medical devices would be allowed to enter the countries according to technological and scientific advance.

Q & A

Thank You!

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