藥品仿單電子化之國際趨勢

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藥品標籤數位化促進暨創新處

大綱

- 電子仿單之定義及趨勢
- 世界各國的電子仿單法規要求
- 日本電子仿單的法規進展
- 歐洲電子仿單的法規進展
- IFPMA建議的仿單電子化之執行步驟

電子仿單之定義

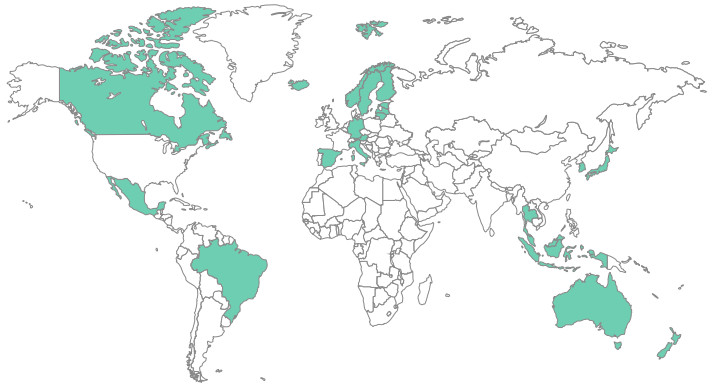
- e-labeling is defined as the dissemination of approved product information for medicinal products including in a dynamic digital format.
- 台灣電子仿單可由食藥署網站之藥品仿單查詢平台查閱

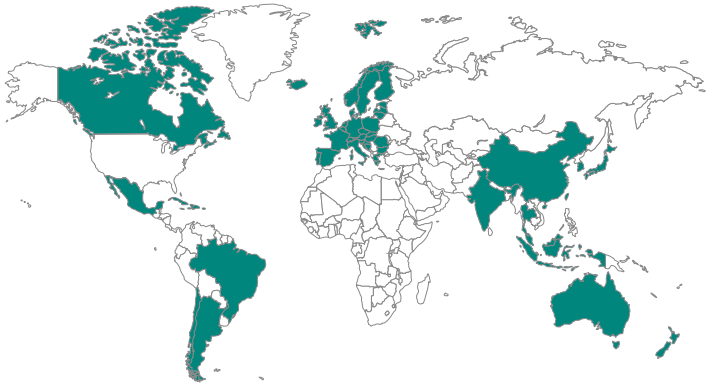
Reference: IFPMA Position Paper published on 7 Feb 2022; https://www.ifpma.org/resource-centre/position-paper-use-of-electronic-labeling/

* IFPMA represents the research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry's 2 million employees research, develop and provide medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.

藥品電子仿單的全球趨勢

2010 — 2020 — 2022 — 2025





LOW ACTIVITY IN THE LAST DECADE

- AUS-NZ allowed Paperless ePI
- BEL•LUX allow paperless for 40 products
- Singapore allows paperless leaflets
- Formation of Inter Association Task Force

SIGNIFICANT INCREASE IN ACTIVITY SINCE 2020

- EMA publishes principles for ePI in Europe
- EC Derogation of 4 more EU markets paperless Hospital products
- **Japan** regulation on transition to paperless ePI
- **Singapore** e-Labeling Guidance published
- 20+ Pioneer Markets experimenting with ePI
- Consultations from Health Authorities in Canada, EMA

INCREASE IN ADOPTION OF ePI SINCE 2020

- More countries moving to paperless ePI
- Increase in EC derogations
- **Move to Paperless PI as a norm** rather than exception
- Adopt data and code standards

2024 政策亮點

越來越多的衛生主管機關允許核准的藥品使用電子仿單，為無紙化電子仿單的實施奠定了基礎。

在全球各區域，電子仿單指南和法規的制定繼續加速。

Key Policy Milestones in 2024

歐盟

- 正在制定的電子仿單法規預計將於2026年底或2027年初針對醫院產品完成，並有18個月的過渡期。對所有成員國來說，過渡到無紙化最有可能是自願的。

海灣合作委員會（GCC）

- 除了強制實施Nashratech電子仿單解決方案（第一階段）針對GCC國家集中註冊的藥品外，沙烏地阿拉伯衛生機構（SFDA）最近宣布其意圖將實施範圍擴展到其他註冊的產品（第二階段）且於2026年12月31日前完成。

拉丁美洲

- 2024年7月12日，巴西衛生主管機關（ANVISA）發布了RDC nº 885/2024，這是第一個在拉丁美洲實施無紙化藥品電子仿單的國家（第一階段：樣品和醫院產品的無紙化）。該法律於2024年9月10日生效。

亞太地區

- 目前允許無紙化的國家（日本、澳洲/紐西蘭、文萊、馬來西亞、新加坡、台灣(限定的藥品品項)）。
- 衛生主管機關有計畫實施電子仿單的國家:泰國、菲律賓、越南和香港的衛生主管機關預計將在2024年年底到2025發布電子仿單指南。

藥品電子仿單的全球法規要求

- 日本是全球第一個國家強制移除處方藥之紙本仿單
- 其他國家(包括新加坡、馬來西亞、**澳洲/紐西蘭等國**)允許電子仿單取代紙本仿單，廠商可自行決定是否移除紙本仿單
- 歐洲(如:比利時、西班牙、葡萄牙等國)也有無紙化仿單的試辦計畫在進行中
- 除了美國、日本、及加拿大已在仿單格式化上要求XML目前歐盟及台灣亦已要求XML的仿單格式

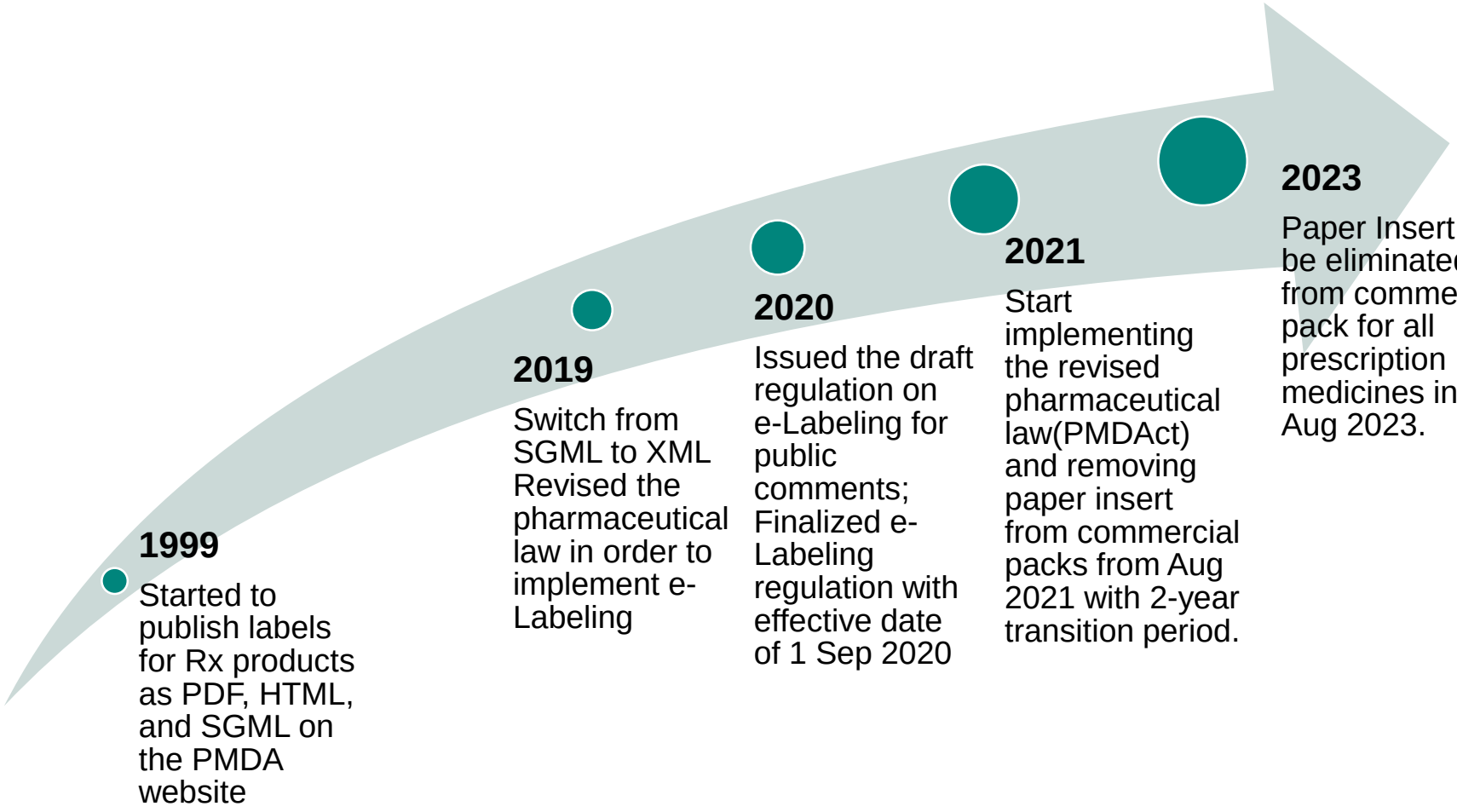
WHAT IS THE LANDSCAPE OF E-LABELING REGULATIONS AROUND THE WORLD?

	National Repository	XML Format Adopted	Elimination of Paper
US	✓	✓	
Canada	✓	✓ Voluntary	Voluntary, to be agreed upon by NRA
EMA	✓	✓	
UK	✓		
Japan	✓	✓	✓ Aug. '21
Singapore			Voluntary
Australia	✓		Paper copies needed for injectables
Chinese Taipei	✓	✓	
China			
Brazil	✓		

Fig.1 – Global overview of selected e-labeling regulations

Reference: IFPMA Position Paper published on 7 Feb 2022; https://www.ifpma.org/resource-centre/position-paper-use-of-electronic-labeling/

日本電子仿單的法規進展



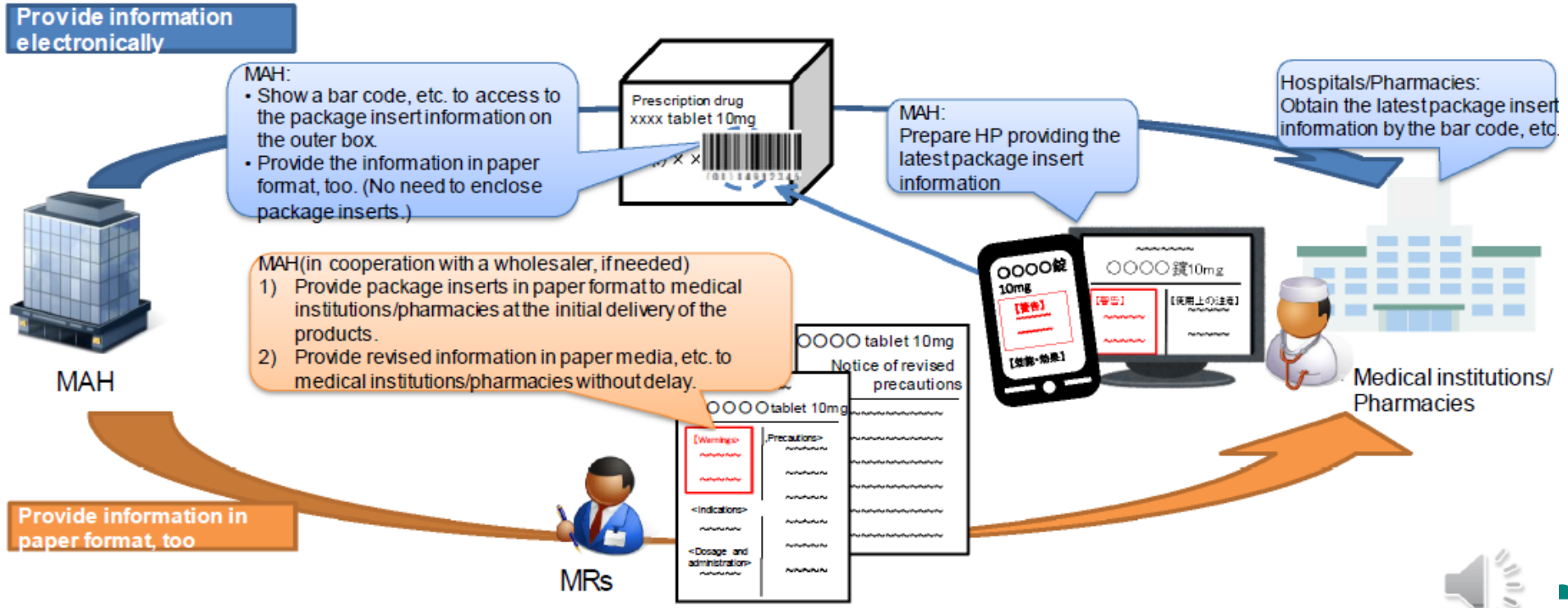
* Source information for Japan’ s e-Labeling sharing:10TH APAC | APAC (apac-asia.com)

Electronic Distribution of Package Insert Information

e-Labeling

From 1 Aug, 2021

- Package inserts shall basically be distributed electronically instead of being enclosed in products.
- In addition to the electronic distribution, package inserts shall be provided in paper format at the initial delivery of drugs/medical devices under the responsibility of a Marketing Authorization Holder and in cooperation with a wholesaler, if needed. Also, a scheme shall be built to provide information to access the latest package insert information shown on the outer box of a product, and revised information is distributed to medical institutions/pharmacies without fail in paper format or other forms.
- For OTC drugs and medical devices for home use that are directly purchased by consumers, package inserts shall be continuously prepared in paper format and enclosed in products to make the information available at the time of use.



Asia Partnership Conference of Pharmaceutical Associations

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Accessibility

Use an app to scan the barcode

Select the document

Package Inserts

Related Documents

Show the latest version of the package insert from the PMDA website.

Show the PMDA web page with links to the related documents.
(Example for human drugs shown here)

onpropriatary Name		●●●
Brand Name		●●●錠10mg/●●●錠20mg
arketing Authorization Holder		▲▲▲製薬株式会社
Package Insert		PDF HTML
Drug Guide for Patients		G_●●●錠10mg/●●●錠20mg
Interview Forms		F_●●●錠10mg/●●●錠20mg
Risk Management Plan (RMP)		○
RMP Materials	For Healthcare Professionals	●●の適正使用ガイド
	For Patients	●●を使用中の方へ ●●カード
History of the Revisions and the Supporting Case Summaries		20XX年X月X日薬生安発XXXX第X号 別紙X［根拠症例］ 20XX年X月X日薬生安発XXXX第X号 別紙X［根拠症例］
Review Report, Reexamination Report, Optimal Clinical Use Guidelines, etc.		審査報告書(20XX年X月X日)

* The actual visual image shown on the smartphone will vary depending on the app used.

歐洲電子仿單的法規進展

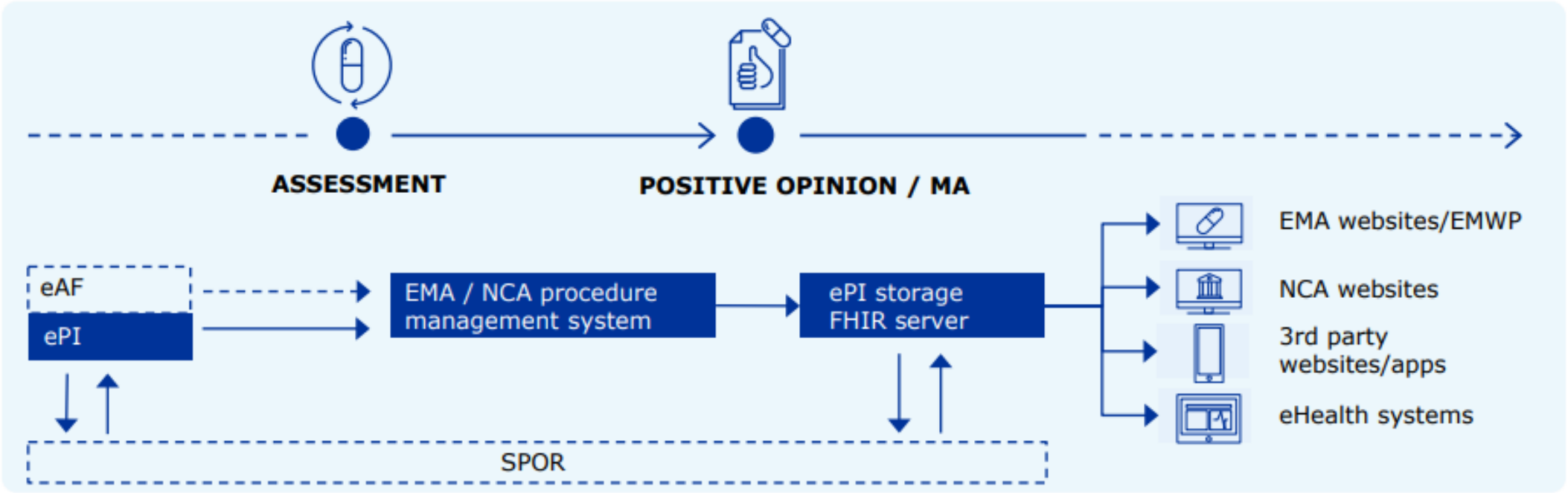
ePI roadmap key facts

- The **ePI initiative** will progress using the ePI key principles as a guideline.
- In December 2021, the **ePI set-up project** closes. It has delivered the EU ePI Common Standard, a proof-of-concept prototype and a roadmap leading to the next project.
- In 2022-2023, the **ePI pilot project** will develop tooling and guidance (the 'minimum viable product') for a pilot in real-world medicines procedures involving CAPs and NAPs.
- Piloting will be followed by phased implementation.

歐洲電子仿單的法規進展

Future vision for ePI in regulatory procedures

ePI will be seamlessly integrated with all EMA/NCA systems supporting medicines assessment.



歐洲電子仿單的試辦方案

Pilot project to test ePI - concluded

EMA and a group of EU national competent authorities tested the use of ePI in a one-year pilot project from July 2023 to July 2024.

The pilot has concluded. Its achievements include:

- Enabling companies to create and manage ePIs during regulatory procedures by using an **ePI authoring tool** on the Product Lifecycle Management Portal
- Making ePIs created during the pilot **publicly available** on the portal and via an application programming interface (API)

To access the ePIs, see:

- Published ePIs (Product Lifecycle Management Portal)
- Application programming interface for ePIs

The pilot covered both centralised and national regulatory procedures.

Participating countries included Denmark, the Netherlands, Spain and Sweden.

ePI for human medicines · PLM

歐洲電子仿單的格式標準

EU ePI Common Standard

ePI uses a semi-structured format, based on a common electronic standard for product information.

The **EU ePI Common Standard** is available, based on **Fast Healthcare Interoperability Resources (FHIR)**, a technical standard describing data formats and elements and an application programming interface for exchanging electronic health records:

- EU ePI Common Standard (on GitHub)

The EU ePI Common Standard has been adopted by the European medicines regulatory network to support the provision of harmonised electronic information on medicines within the EU.

IFPMA建議的仿單電子化之執行步驟

1. 建立電子仿單資料庫
2. 建立電子仿單和條碼之連結
3. 彈性降低紙本仿單之法規要求
4. 移除紙本仿單之法規要求
5. 建立結構化電子仿單及標準以利與其他電子系統連結

Reference: IFPMA Position Paper published on 7 Feb 2022; https://www.ifpma.org/resource-centre/position-paper-use-of-electronic-labeling/

目前觀察到世界各國正在進行中的仿單電子化之執行步驟

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Thank You