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Current and planned e-labeling initiatives in Japan

KURIHARA Sayaka

PMDA

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Today's Agenda

- Revision of PMD Act
- Benefits of E-labeling
- Future E-labeling

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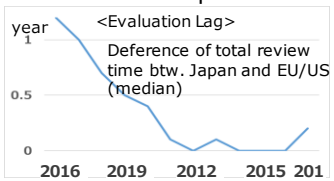
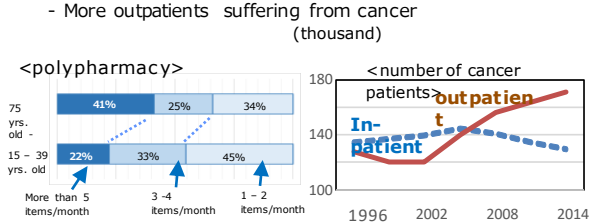
Revision of Pharmaceuticals and Medical Devices Act

《Basic Policy》

From 1 Sep, 2020

1 To provide better medical products safely, promptly and efficiently.
2 To improve a pharmaceuticals provision system for patient's secure access in familiar community

	Modernizing Regulatory System	Value of Community Pharmacies/Pharmacists	Prevention of Illegality
Current Status	➢ Good performance in review process  estimated by PMDA ➢ Surrounding change Advanced technology – Needs for innovative products Globalization ➢ Unmet medical needs	➢ Expectation of patients for improving their service ➢ Increasing importance of appropriate treatment with medicines - More concern about polypharmacy along with aging - More outpatients suffering from cancer  	➢ Unfavorable events - Manufacturing through unapproved process - False/puffery advertising - Distribution of a falsified product - Fraudulent procurement of a certification to import a product
Issues	➢ To facilitate patient access - To improve regulation in terms of predictability, international harmonization and efficiency. - To enhance safety measure	➢ To recommend some of services ➢ To help patients choose his/her pharmacy	➢ To set countermeasures
Proposed Measures	➢ Introduction of new approval schemes into the Act - SAKIGAKE - Conditional early approval - Priority review of unmet medical needs such as products for pediatrics - modified scheme for a technology which requires continuous amelioration such as AI ➢ **Safety measure** **- Electronic provision of package insert** **- Bar code display**	➢ Recommendation of additional services - Following up adherence and condition of a patient - Information sharing with other healthcare professionals ➢ To establish a display system related to pharmacy's feature	- Enrichment of governance structure of a company - Levy system against profit stemmed from false/puffery advertising - To legislate a certification system for import

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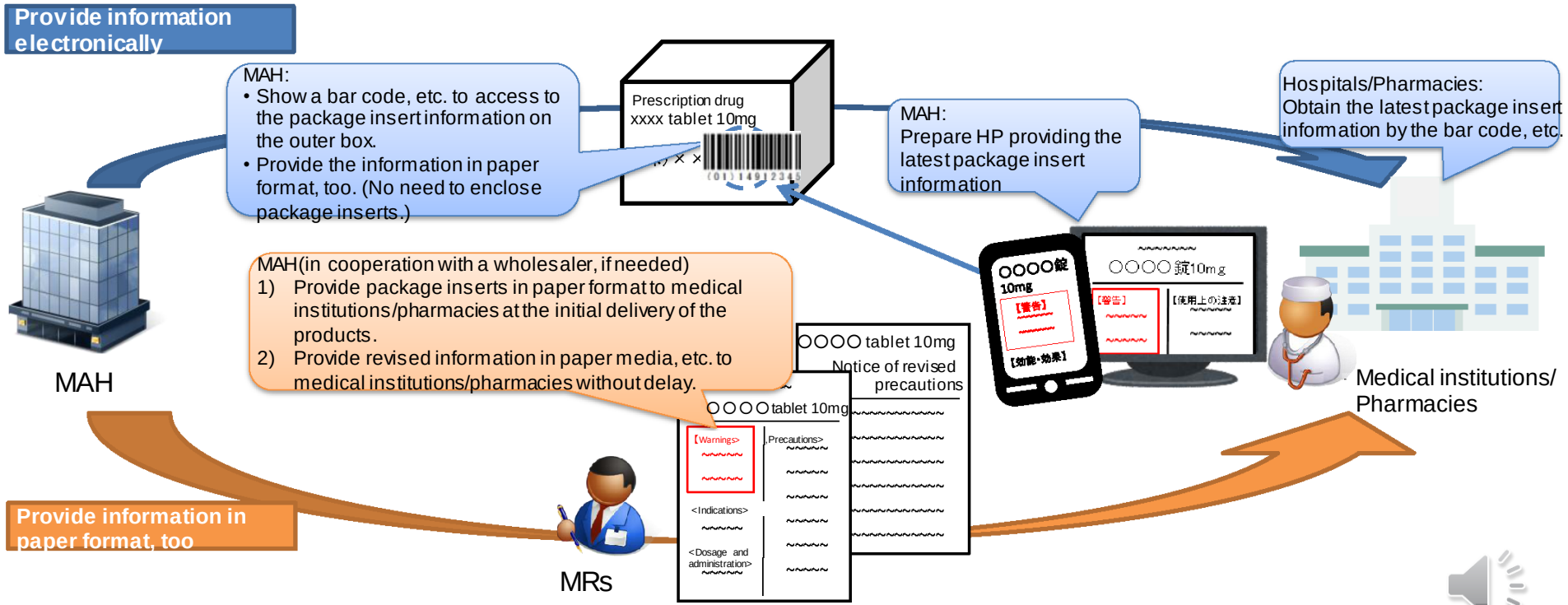
Electronic Distribution of Package Insert Information

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.



Bar Code Labeling of Drugs/Medical Devices

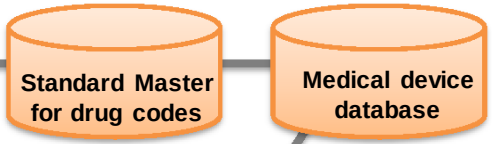
From 1 Dec, 2022

- For securing medical safety, measures to improve traceability from manufacturing/distribution to clinical settings are important, such as managing product information, tracking of usage records, preventing mix-ups. With an aim to enhance safety by these measures, bar code labeling based on the international standards shall be required for immediate containers/wrappings/retail packages of drugs/medical devices.
  - Effective/stepwise implementation according to the type of drugs/medical devices and the current status of use of coding including OTC drugs shall be considered in the Bar code labelling requirement.
  - Also, safety measures using bar code labeling at clinical settings shall be promoted, as well as registration of production information in the database by MAHs, along with mandatory bar code labeling.

<GS1 bar code labeling on drugs/medical devices>

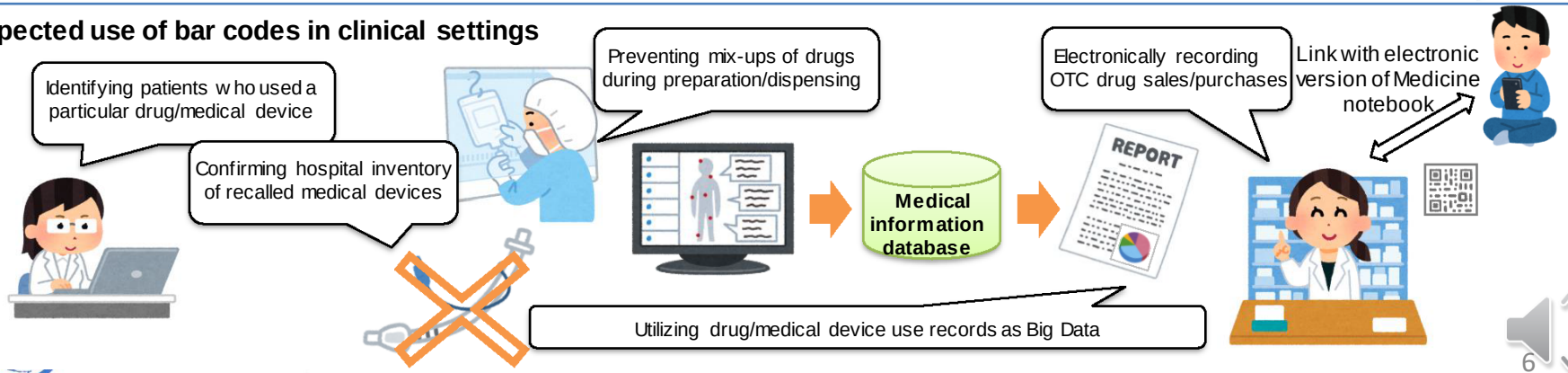
Product codes of ethical drugs are already 100% indicated.
Expiry dates, lot Nos. shall be indicated by Apr. 2021 in principle.

<Registration of product information in databases>



Using bar codes in logistics/ clinical settings

Expected use of bar codes in clinical settings



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Benefits of e-labeling

- **Accessibility**
- **Efficiency**
- **Ecological**
- **Searchability**
- **Arrangeability**

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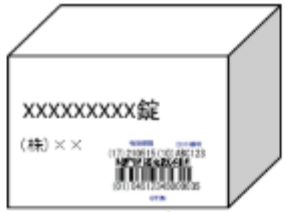
Accessibility



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.

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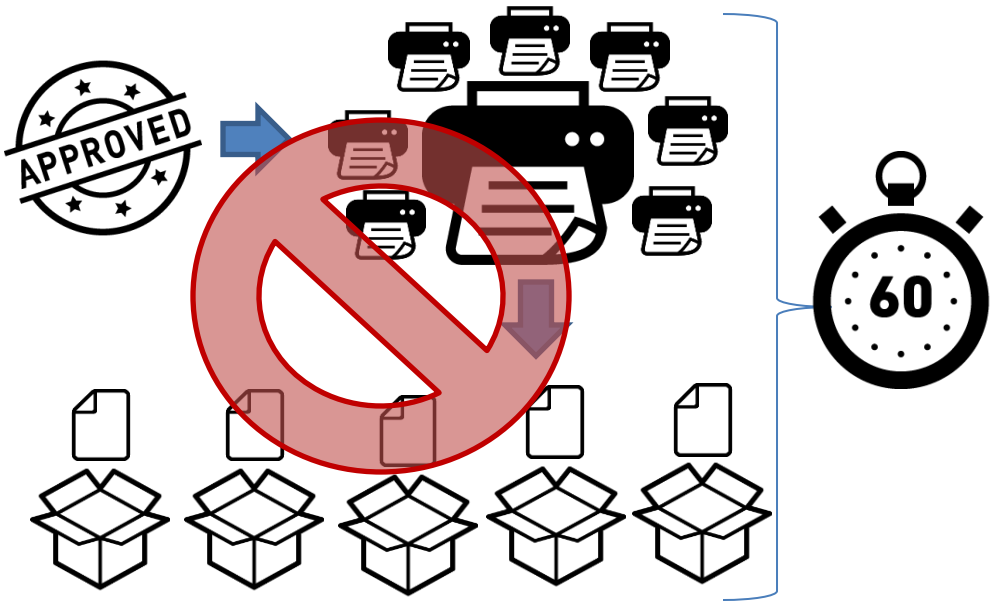
Efficiency and Ecological



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Benefits of e-labeling

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Searchability
-Labeling format in Japan-

Labeling (PDF, XML)

- DATE OF PREPARATION OR REVISION
- STANDARD COMMODITY CLASSIFICATION NUMBER OF JAPAN
- APPROVAL NUMBER, DATE OF INITIAL MARKETING IN JAPAN
- STORAGE, SHELF LIFE
- THERAPEUTIC CATEGORY
- REGULATORY CLASSIFICATION
- NAME OF PRODUCT
- WARNINGS
- CONTRAINDICATIONS (This drug is contraindicated to the following patients.)
- COMPOSITION AND PRODUCT DESCRIPTION
- INDICATIONS
- PRECAUTIONS CONCERNING INDICATIONS
- DOSAGE AND ADMINISTRATION
- PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION
- IMPORTANT PRECAUTIONS
- PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS
- INTERACTIONS
- ADVERSE REACTIONS
- INFLUENCE ON LABORATORY TESTS
- OVERDOSAGE
- PRECAUTIONS CONCERNING USE
- OTHER PRECAUTIONS
- PHARMACOKINETICS
- CLINICAL STUDIES
- PHARMACOLOGY
- PHYSICOCHEMICAL PROPERTIES
- PRECAUTIONS FOR HANDLING
- APPROVAL CONDITIONS
- PACKAGING
- REFERENCES
- REFERENCE REQUEST AND CONTACT INFORMATION
- PRECAUTION CONCERNING HEALTH INSURANCE BENEFITS
- MARKETING AUTHORIZATION HOLDER, etc.

AND/NOT/OR

https://www.pmda.go.jp/PmdaSearch/iyakuSearch/
（Only in Japanese）

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Benefits of e-labeling

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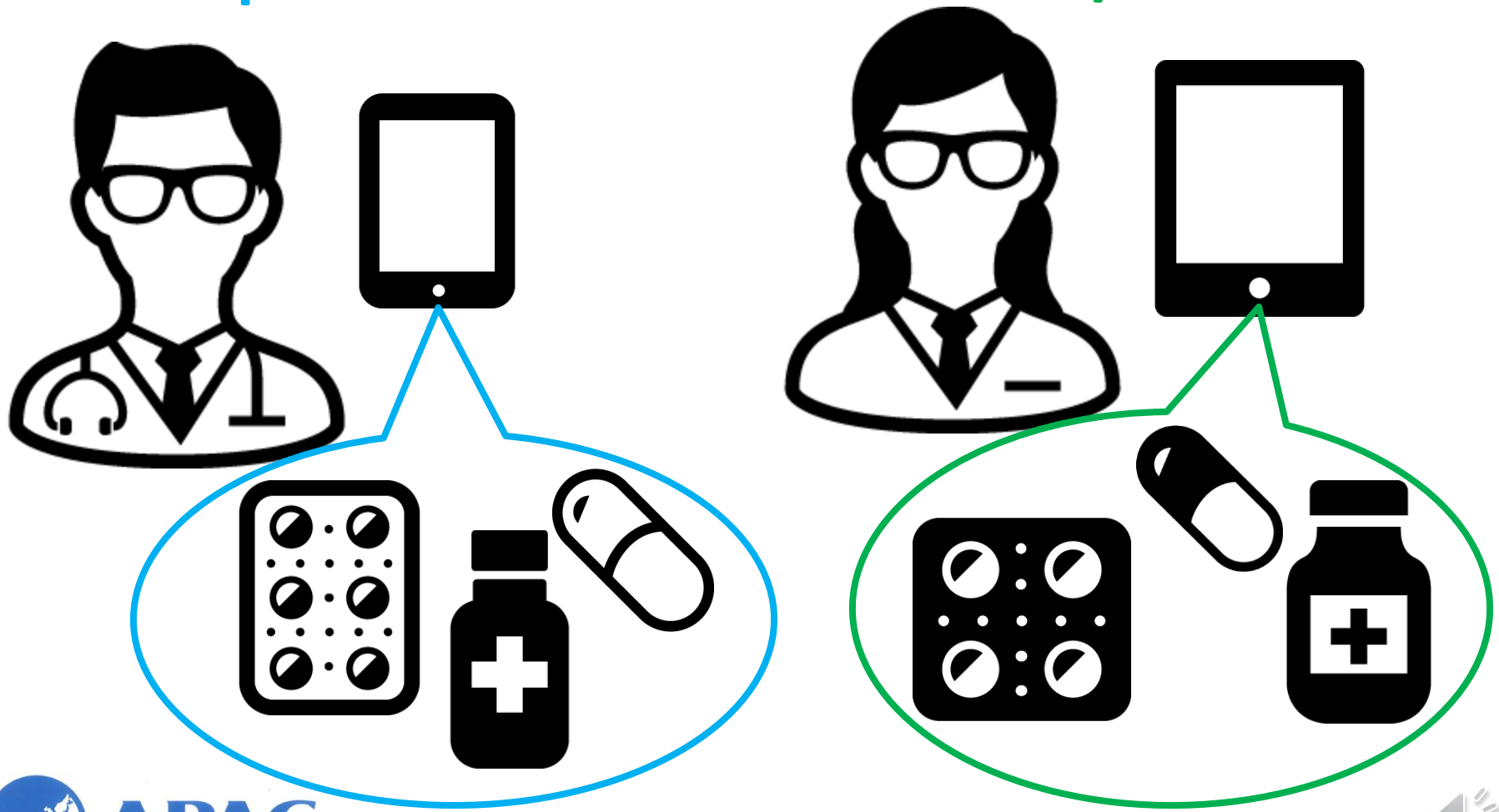
Arrangeability

Hospital A

Hospital B



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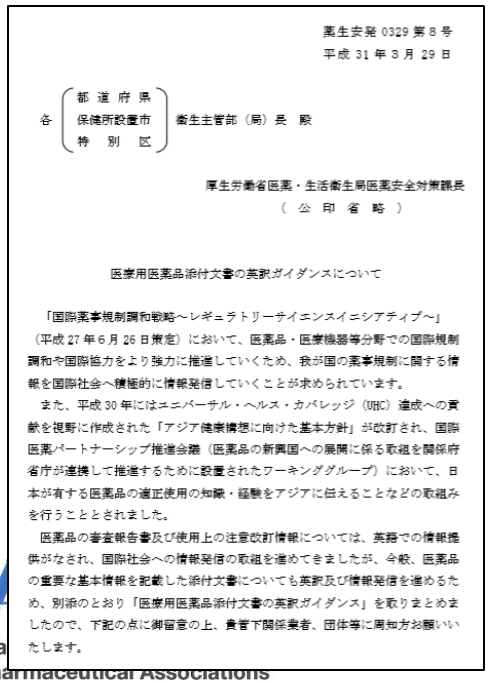
English Version of Japanese Labeling

Notification on English translation

English translation guidance for prescription drugs, PSEHB/PSD Notification No. 0329-8, 29 March, 2019

- In order to promote regulatory harmonization and international collaboration, MHLW and PMDA declare to disseminate regulatory information to the other countries.
- To share knowledge and experience on proper use of medicines to Asia



薬生安発 0329 第 8 号
平成 31 年 3 月 29 日

各 都道府県 保健所設置市 特別区 衛生主管部（局）長 殿

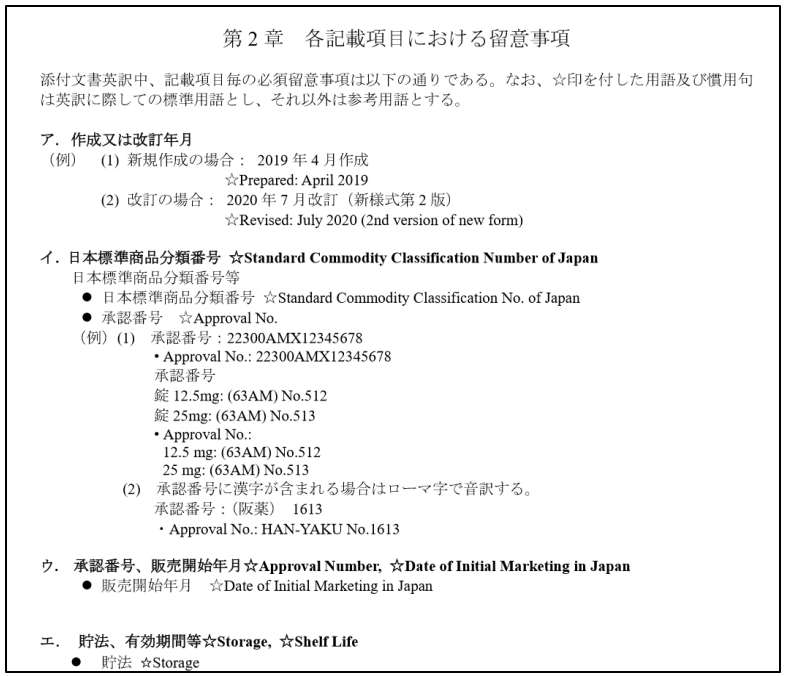
厚生労働省医薬・生活衛生局医薬安全対策課長
（ 公 印 省 略 ）

医療用医薬品添付文書の英訳ガイダンスについて

「国際薬事規制調和戦略～レギュラトリーサイエンスイニシアティブ～」（平成 27 年 6 月 26 日策定）において、医薬品・医療機器等分野での国際規制調和や国際協力をより強力に推進していくため、我が国の薬事規制に関する情報を国際社会へ積極的に情報発信していくことが求められています。

また、平成 30 年にはユニバーサル・ヘルス・カバレッジ（UHC）達成への貢献を視野に作成された「アジア健康構想に向けた基本方針」が改訂され、国際医薬パートナーシップ推進会議（医薬品の新興国への展開に係る取組を関係府省庁が連携して推進するために設置されたワーキンググループ）において、日本が有する医薬品の適正使用の知識・経験をアジアに伝えることなどの取組みを行うこととされました。

医薬品の審査報告書及び使用上の注意改訂情報については、英語での情報提供がなされ、国際社会への情報発信の取組を進めてきましたが、今般、医薬品の重要な基本情報を記載した添付文書についても英訳及び情報発信を進めるため、別添のとおり「医療用医薬品添付文書の英訳ガイダンス」を取りまとめましたので、下記の点に御留意の上、貴管下関係業者、団体等に周知方お願いいたします。



第 2 章　各記載項目における留意事項

添付文書英訳中、記載項目毎の必須留意事項は以下の通りである。なお、☆印を付した用語及び慣用句は英訳に際しての標準用語とし、それ以外は参考用語とする。

ア．作成又は改訂年月
（例） (1) 新規作成の場合： 2019 年 4 月作成
☆Prepared: April 2019
(2) 改訂の場合： 2020 年 7 月改訂（新様式第 2 版）
☆Revised: July 2020 (2nd version of new form)

イ．日本標準商品分類番号 ☆Standard Commodity Classification Number of Japan
日本標準商品分類番号等
- 日本標準商品分類番号 ☆Standard Commodity Classification No. of Japan
- 承認番号 ☆Approval No.

（例）(1) 承認番号：22300AMX12345678
• Approval No.: 22300AMX12345678
承認番号
錠 12.5mg: (63AM) No.512
錠 25mg: (63AM) No.513
• Approval No.:
12.5 mg: (63AM) No.512
25 mg: (63AM) No.513
(2) 承認番号に漢字が含まれる場合はローマ字で音訳する。
承認番号：（阪薬） 1613
・Approval No.: HAN-YAKU No.1613

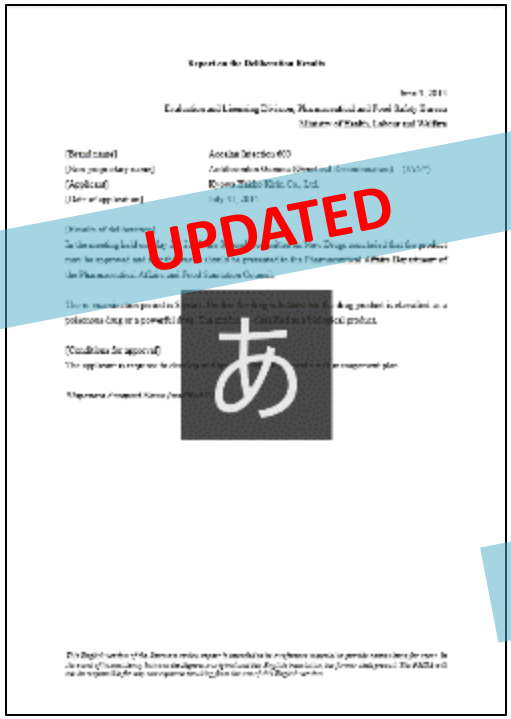
ウ． 承認番号、販売開始年月☆Approval Number, ☆Date of Initial Marketing in Japan
- 販売開始年月 ☆Date of Initial Marketing in Japan

エ． 貯法、有効期間等☆Storage, ☆Shelf Life
- 貯法 ☆Storage

https://www.pmda.go.jp/files/000229048.pdf
(Only in Japanese)

https://www.pmda.go.jp/files/000229049.pdf
(Only in Japanese)

Information Update



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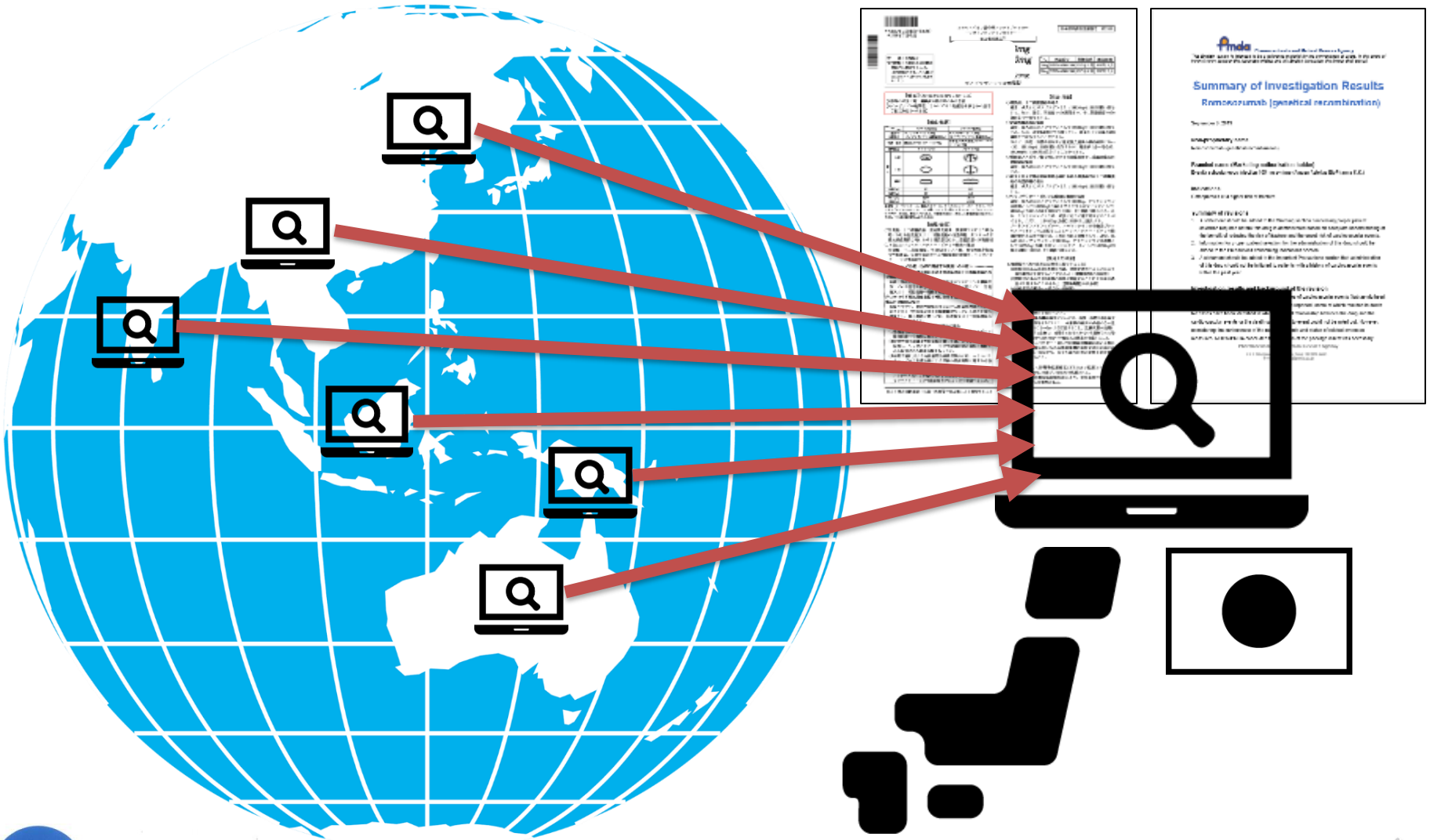
Future E-labeling



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Conclusion

E-labeling can be utilized for each regulatory authorities in the world.

Patient access faster!

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Thank you for your attention!

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