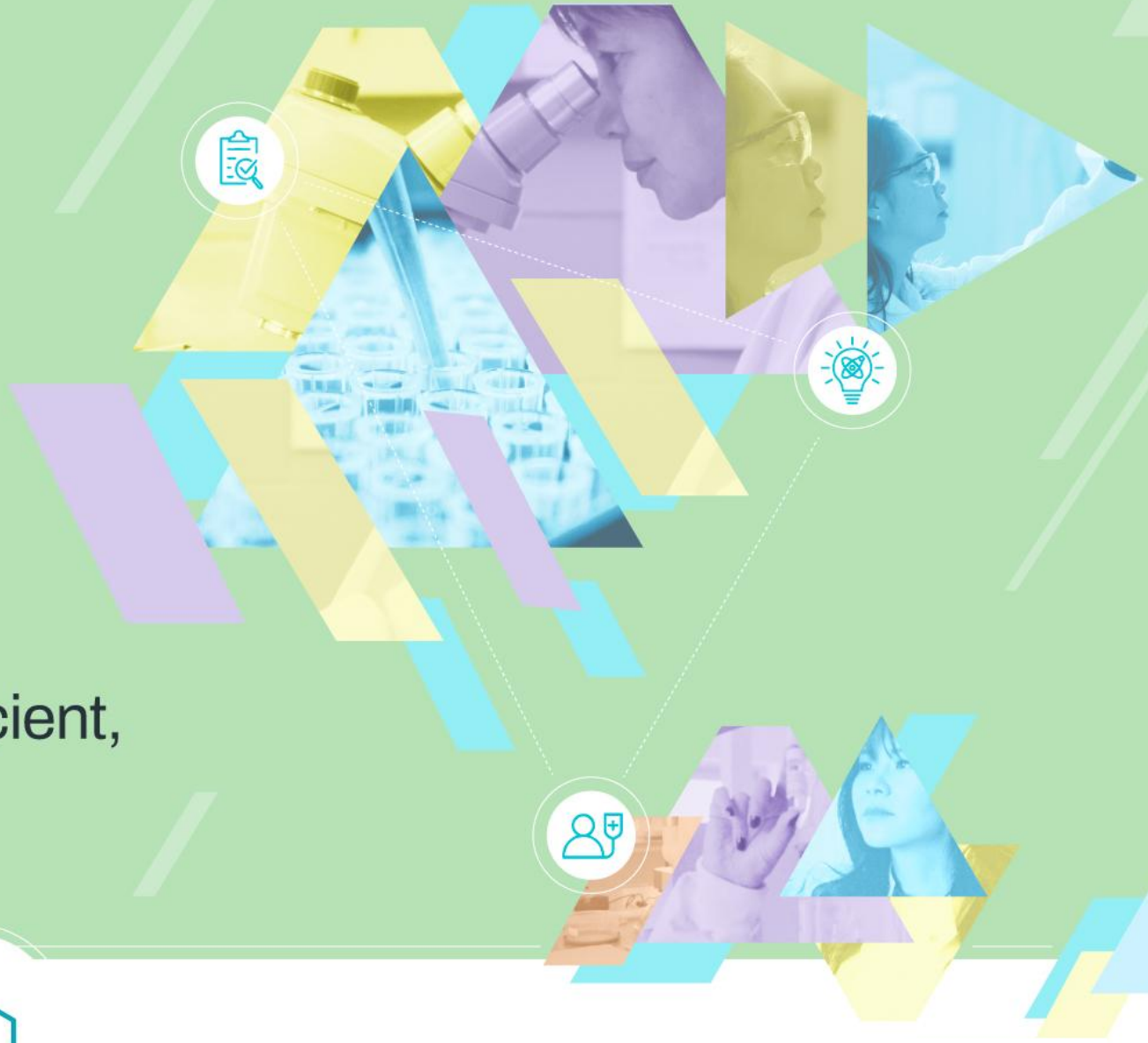
03-06 December 2024

ARC 2024

ASIA REGULATORY CONFERENCE

EVOLVING LANDSCAPES

Asia's role in driving a more efficient, innovative and patient-centric regulatory environment



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Asia's role in driving a more efficient, innovative and patient-centric regulatory environment

Welcome to Day 3

HOT TOPICS

- E-labelling as a pathway to a future Universal Label
- Combination products for advanced therapies and biologics

Organized by IFPMA

In partnership with Medicines Australia

Thank you for joining! A few guidelines for participants

The conference is held in English.

The detailed conference programme and speakers' biographies are available on arc.ifpma.org.

All participants are muted. Please use the Q&A box to raise questions to the speakers. If a question you would like to ask has already been raised, you can also “like” that question.

Polls will be used during the sessions. These will appear on screen.

We encourage you to join all conference days. There is still time to register for other sessions.

The conference is recorded. All speaker presentations and videos will be made available on the website after the conference.

E-labelling as a pathway to a future Universal Label

Moderators: Wan Lee Chow & Tham Vo

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E-labelling as a pathway to a future Universal Label

Moderators :

Wan Lee Chow
Head of Regulatory Sciences (Malaysia), Pfizer

Tham Vo
Senior Manager Policy, Medicines Australia

Presenters :

Rie Matsui
Senior Director, Regional Labeling Head for APAC, Head of External Liaison, International Labeling, Global Regulatory Science , Pfizer R&D Japan

Helen Critchley
Country Regulatory Head – Australia & NZ, Sanofi

Panelists :

Pascal Aulagnet
Market and regulatory engagement team lead, Pfizer

Carla Cartwright
Head Global Digital and Regulatory Policy, Johnson & Johnson

Monica Ferrie
Chief Executive, Genetic Support Network of Victoria

Tony Manderson
Director, Therapeutic Goods Administration

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Current status of e-labeling implementation in the Asia Pacific region and what is on the horizon

Presented by Rie Matsui, R. Ph.

Senior Director, Regional Labeling Head for APAC, Head of External Liaison, International Labeling, Global Regulatory Science

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Agenda

- What is e-labeling?
- Regulatory Agility: Case of e-labeling for COVID-19 vaccines
- Points to Considers for e-labeling initiatives
- Outlook of e-labeling Initiatives in Asian region
- Integrated Labeling of the Future
- Next steps in Asian region

What is e-labeling?

- Availability of the latest labeling on a publicly accessible website (product information is easily accessible online)
- Accessible, reader friendly format, e.g. scanning a code; resizable text; multiple languages; searchable content
- Eliminating paper labeling from commercial pack
- Structured content, e.g. FHIR XML
- Interoperability between systems, e.g. share product information across wearable, ePrescription, and eHealth record

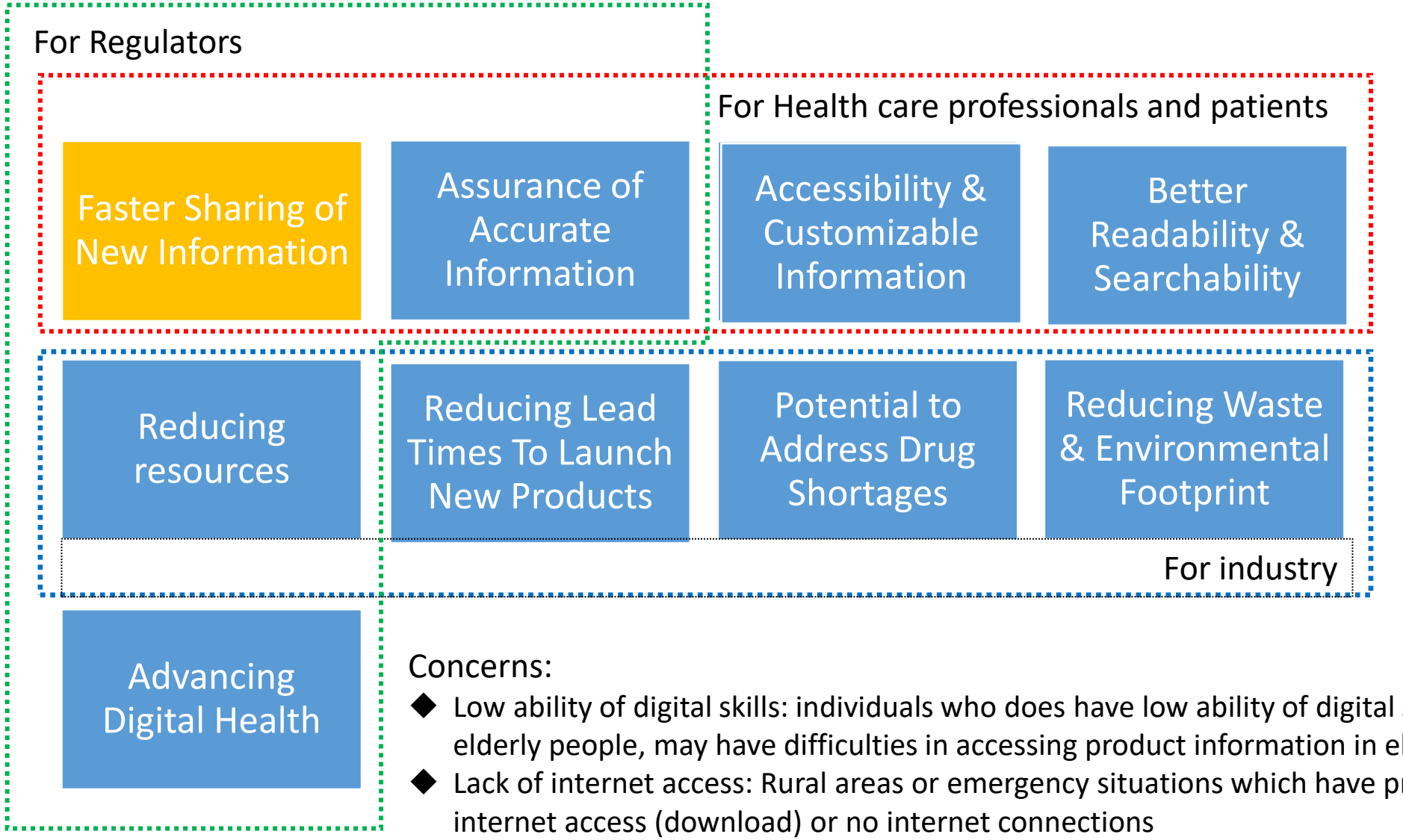
Why is important?

E-Labeling can improve:

- Accessibility & understanding of most recent product information for patients & HCPs
- Adherence
- Patient outcomes
- Improve efficiency and reduce paper waste

E-labeling is the availability of **the latest approved product information electronically on publicly accessible website via smart devices**. E-labeling would be in **a common structured format using global standards to allow efficient and seamless information flow** amongst manufacturers, regulators, HCPs, and patients. E-labeling would eventually replace the paper product information leaflet that are placed within commercial packs. (*From the APAC e-labeling position paper*)

Benefits of e-labeling



Concerns:

- Low ability of digital skills: individuals who does have low ability of digital skills, such as elderly people, may have difficulties in accessing product information in electronic way
- Lack of internet access: Rural areas or emergency situations which have problems with internet access (download) or no internet connections

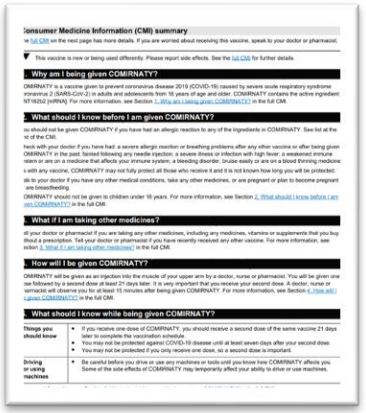
Regulatory Agility: Case of e-labeling for COVID-19 vaccines

Instead of inserting a paper labeling, *"e-labeling"* was introduced for COVID-19 vaccines

- QR code was located on the product carton box
- Scanning of the QR code directed users to the company COVID-19 landing page
- There was a dropdown list* by country and options available for each country page (depending on local requirements)
- Direct to PDF (labeling)
  - Linked to an external webpage e.g., HA website, company product page
  - Provided option to add local specific information/documents as requested by local HA

QR code for e-labeling

www.cvdvaccine.com and/or
https://www.[redacted]global.com



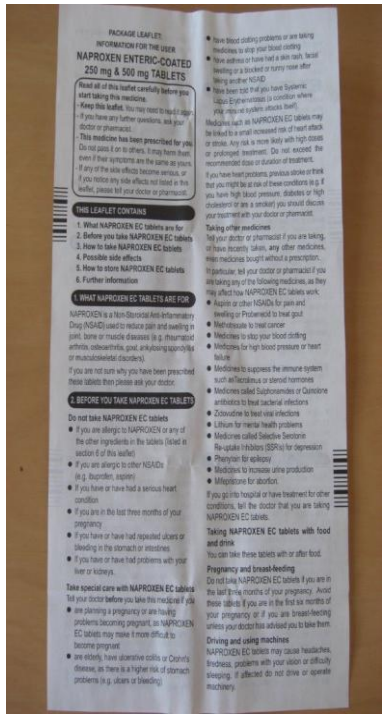
* There is a separate website for Japan.

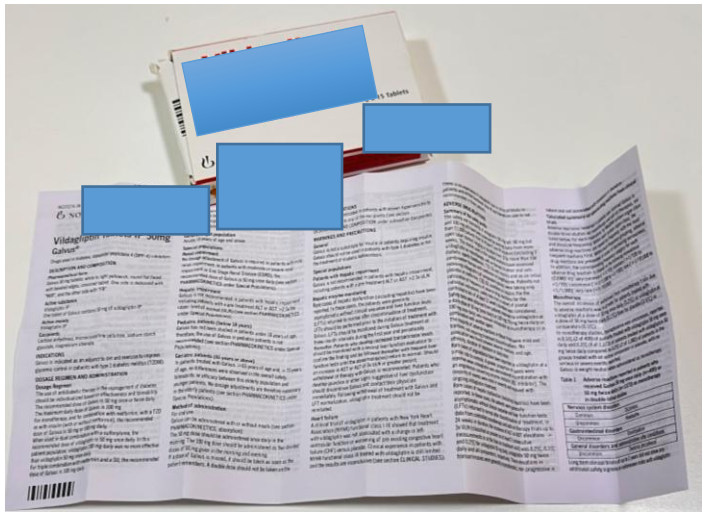
- **Around 70 markets' labels were available on the website**
- **Labeling had been updated approx. 1-3 times/month for the first 6 months**

The code and website are just a part of e-labeling elements; i.e., makes it easy to access the e-label. The next step is to make the *e-label itself personalized/more useful.*

Points to Consider:
Eliminating paper labeling from commercial pack

Labeling Documents in the Commercial Pack





Depending on the country, the pack may contain Healthcare Professional Information (e.g. U.S., Japan and India) or patient information (e.g. EU)

In Asia, mostly labeling for HCPs is inserted in a commercial pack.

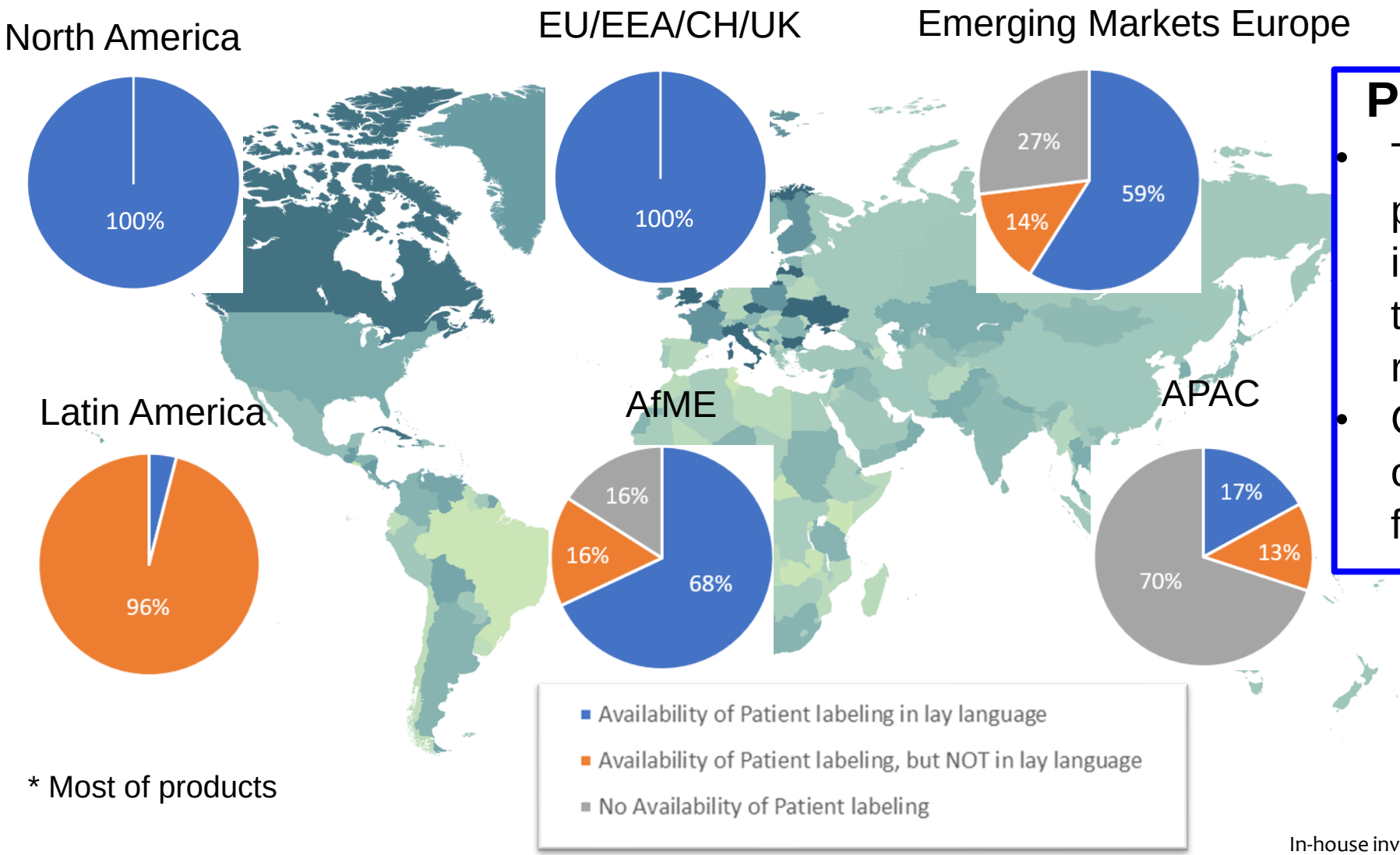
Points to Considers

Critical roles of packaging insert

- Can be served as a tangible packaging functional component
- Aid steadiness of the product in container during transportation
- Can provide some degrees of light protection and thermal insulation

Packaging Risk Assessment is a MUST Prior to removing paper labeling.

Points to Consider:
Outlook of Availability of Patient Centric Product Information for Prescription medicines*



Point to Considers

- The availability of patient centric labeling is only around 30 % of the markets in Asian region.
- Currently, the adoption of e-labeling is mainly for health professionals.

* Most of products

In-house investigation as of Oct 2023

Outlook of e-labeling Initiatives in Asian region

As of June 2024

	Regulation/ guidance issued	Type of in-scope products	E-labeling platform	Easy accessibility to e-label via machine-readable code	Eliminating paper labeling from a commercial pack	Structured contents of labeling such as XML	Interoperable e-labeling
Japan	Feb 2021	Rx	✔ (HA)	✔ GS1 barcode App is used	✔All Rx	✔	NA
Singapore	Apr 2021	Rx	✔(Company or 3rd party)	✔Voluntary: company choice	✔ Voluntary	NA	NA
Taiwan	Dec 2021(pilot) Sep 2023(official)	Some injectables/ Oral administration (vaccine, contrast media)	✔ (HA)	✔Voluntary: QR	✔ Voluntary	✔	In discussion
Korea	Dec 2022(pilot) Jan 2024(official)	Hospital Injectables	✔(Company or 3rd party)	✔Voluntary: QR (Pilot ongoing)	✔ Voluntary: Pilot ongoing	NA	NA
Malaysia	Apr 2023	Biologic, New Drug Product, Generic Product Containing Scheduled Poison for Rx	✔(HA)	✔Voluntary: QR	✔Voluntary	NA	In discussion
Thailand	Jun 2023	All products	✔ (HA)	✔Voluntary: company choice	✔Voluntary: Only HCP labels	NA	In discussion
Indonesia	Sep 2023	Vaccines, injectables (1st phase), then other Rx (2nd phase), some OTCs (3rd phase)	✔ (HA) (pilot to be started)	✔Pilot to be started (2D barcode, app from HA)	✔Voluntary: Pilot to be started.	NA	NA

→ Universal Labeling

E-labeling initiatives in Asia

SINGAPORE:
- HSA issued a final guidance on labeling **in April 2021**
- Companies voluntary implemented e-labeling where

KOREA:
- MFDS issued e-labeling pilot guidance in **December 2022**.
- E-labeling pilot of pharmaceuticals started in 3.
- get products are tions only used in ical institutions - paper rt can be removed.

JAPAN:
- **In 2019**, Pharmaceuticals and Medical Devices Act was amended to replace paper labeling.
- GS out lab
- **Pa rer 20**

TAIWAN.
- The public and consumers can search the labeling document in either web view, pdf, or XML format.
- TFDA announced the guidance for using e-labeling with **paperless for** medicinal products selected prescription product categories **in Sep 2023**.
- **FHIR e-labeling** is planned

MALAYSIA:
- NPRA issued Guideline on e-labelling for Pharmaceutical Product **in April 2023**.
- It is voluntary for companies to implement labels nee the pack.

INDONESIA:
- BPOM issued Guidance on Implementation of e-labeling pilot project in **Sep 2023**.
- In the Pilot Project, e-labeling is available on BPOM website via serialization Barcode (QR or GS1 data matrix) with **BPOM mobile app.**

THAILAND:
- The Thai FDA officially announced e-labeling has been fully implemented for new registration via e-submission since **June 2023.**

Integrated Labeling of the Future

FHIR

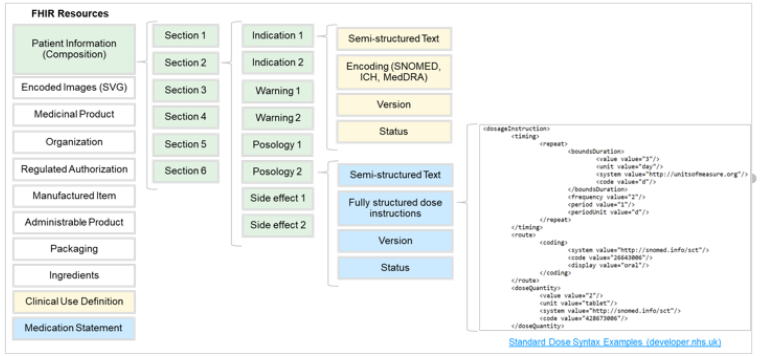
Having labeling information only available as .doc (Word) or .pdf files is restrictive as they are “unstructured”. The files cannot be used “digitally”

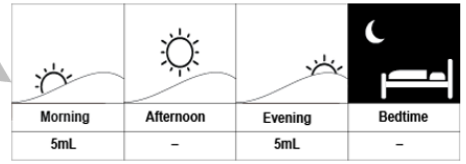
Creation of labeling in an international electronic common standard which is HL7 FHIR offers huge opportunity for further digital transformation

- → Linkage with Electronic Health Records
- → Production of tailored (personalised) labels
- → Automated creation of other materials
- → Provision of real world evidence possible
- → Level five for the second level of bullets

FHIR e-labeling is being adopted in the EU, US and Jordan.

FHIR is interoperable with other eHealth systems





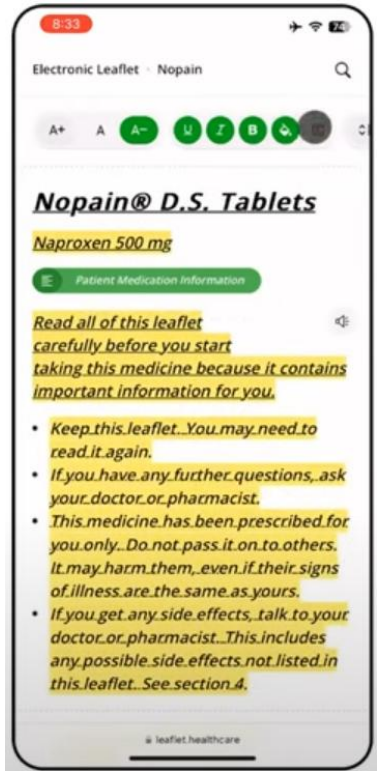
Patient Medication Instructions | Medication | FDB (First Databank)

FHIR has been adopted for the healthcare system in many markets in Asia. <e.g.> India

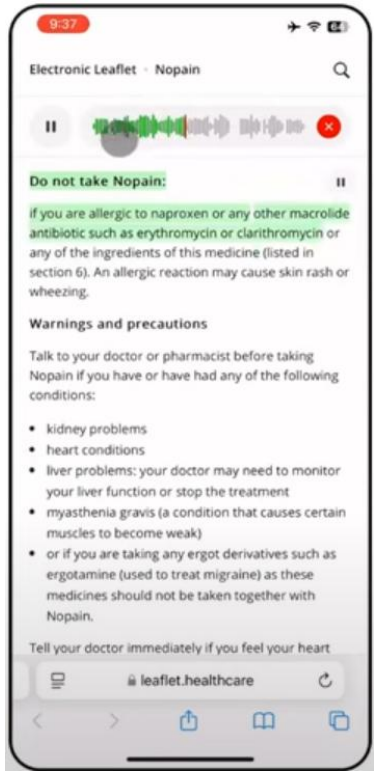
- Biggest FHIR based healthcare project in the world (abmd.in) (290MM patients covered) https://abdm.gov.in/
- ABDM FHIR IG here: https://nrces.in/ndhm/

FHIR facilitates accessibility and multimedia

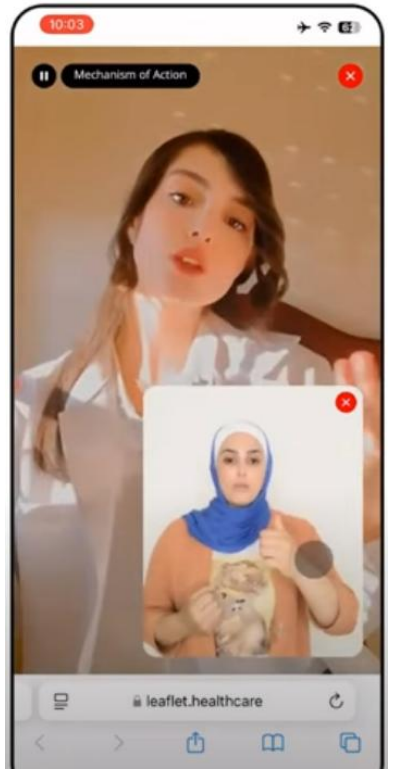
Jordan FDA's ePI app sets a new bar for the application of accessibility



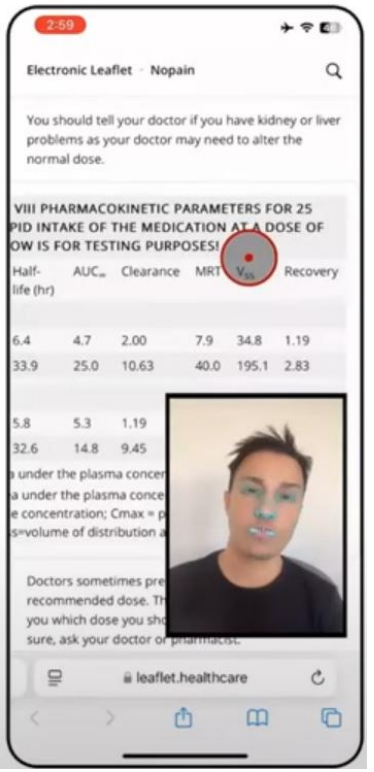
Control text size, dark mode, appearance



Text to speech



Sign language



Face navigation

21.10.2024 | ePI on FHIR: Shaping the Future of Global Healthcare - Gravitate Health

Next steps in Asian region

To encourage the increased uptake in the availability of e-labeling - more companies, more products, more e-labels.

- e-labeling initiatives are implemented on a voluntary basis in many markets in Asia.

To advocate for the implementation of FHIR e-labeling as the international electronic common standard across Asia.

- The adoption of HL7FHIR for the healthcare system has been progressing in many markets in Asia.

To encourage the important introduction of patient centric e-labeling.

- The availability of patient centric labeling is only around 30 % of the markets in Asian region. Currently, the adoption of e-labeling is mainly for health professionals.

To discuss the universal labeling for sustainability

- Machine readable code for e-labeling promote supply chain flexibility (to allow the same artwork to be shared globally) and the removal of paper PI promote sustainability.

Thank you

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PANEL DISCUSSION

Carla Cartwright
Head Global Digital and Regulatory Policy (JnJ)

Monica Ferrie
CEO of Genetic Support Network of Victoria

Tony Manderson
Director, Scientific Operations and Management Section (TGA)

Moderator
Wan Lee Chow
Head of Regulatory Sciences, Malaysia (Pfizer)

QUESTIONS AND ANSWERS

We encourage you to use the Q&A box to raise questions to the speakers.

If a question you would like to ask has already been raised, you can also “like” that question.

Key takeaways

- Dynamic progress for e-labeling initiatives such as issuance of e-labeling guidance in Asian region has been made for the last few years.
- The implementation of FHIR e-labeling should be advocated as the international electronic common standard across Asia.
- The availability of patient centric labeling is only around 30 % of the markets in Asian region. The important introduction of patient centric e-labeling should be encouraged.

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Session 2: Universal Labelling Opportunities & Challenges

Moderator: Tham Vo, Senior Manager Policy (Medicines Australia)

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Universal Labelling
Opportunities & Challenges

Presented by Helen Critchley

Country Regulatory Head – Australia & NZ (Sanofi)

What is the Concept of Universal Labelling?

‘Global’ Pack

- Only critical information to identify product and ensure correct storage is on label with option for use of standard iconography

Acceptable in Multiple Regions

- No country specific information on pack
- Patients easily able to identify products when travelling internationally

Digital Country Specific Information

- Up to date information including safety updates accessible in real time via QR/ datamatrix codes or future technology solution

EU Blue Box Example of Country Specific Information

Why do we need to Evolve beyond e-PI?

Pandemic Preparedness

- Use of Universal labels were critical to manage supply during COVID

Equity of Access

- Simplification of supply logistics to better support resolution of medicines shortages due to country specific pack requirements

Sustainability

- Reduce medicines packaging waste to minimize impact on the environment

How can Universal labelling Benefit Patients?

Future Digital Health Ecosystem

- Digitization in Healthcare is rapidly progressing globally
- Medicines labelling needs to evolve to be fit for future

Improved Health Literacy

- Standard iconography to communicate key messages for safe and effective medicines use
- Builds on e-PI to allow patients to access additional support materials/formats

Reliance

- Allowing multi-country use of the same pack benefits access for patients and HCP
- Simplifies global monitoring and surveillance of marketed products

Opportunities & Challenges

- **Technological advances are occurring at a fast and furious pace**
  - Other industry sectors such as banking and home appliances have rapidly accelerated their digital approach during/post COVID with widespread use of QR codes
  - Medicines are becoming more complex making health literacy a critical factor for safe use to achieve optimal clinical outcomes with new technologies potentially providing more options
- **Medicines labelling regulations in most countries remain reflective of a pre-digital era where printed packaging was the only option**
  - ICH has harmonized many aspects of the requirements for quality, safety and efficacy data but medicines labelling has not been addressed
    - For prescription medicines a printed dispensing label is often the key information accessed by patients
    - When administered in hospital setting patients may not receive the original medicines pack
- **Changing medicines legislation to achieve harmonisation can be time consuming and complex, but brings benefits for all stakeholders by enabling better use of resources to drive innovation**
  - Globalization and harmonisation are a key focus for both industry and regulators
  - Reviewing the purpose and role of printed information in a rapidly evolving digital ecosystem is essential to optimize patient care

Thank you

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PANEL DISCUSSION

Moderator
Tham Vo
Senior Manager Policy
(Medicines Australia)

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Market and regulatory engagement team lead (Pfizer)

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Virtual coffee/tea break

Combining Strengths: Preparing Regulatory Systems for Combination products for advanced therapies and biologics

Moderators

Louise Bisset
MHRA

Rama Sethuraman
Roche, IFPMA

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Setting the scene
Global perspectives on regulatory developments for Drug-Device Combination Products (DDCPs)

Presented by Kevin Klein

Exon consultancy

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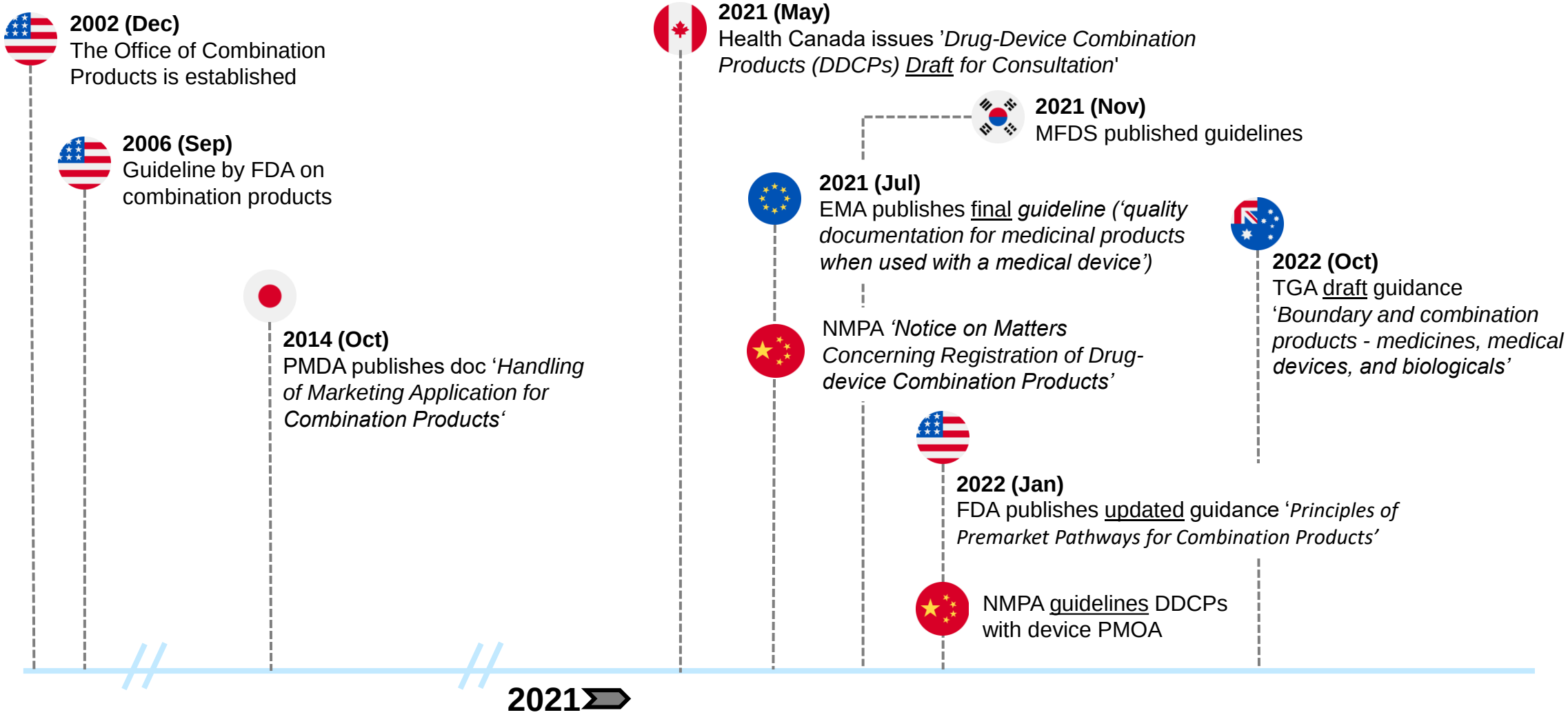
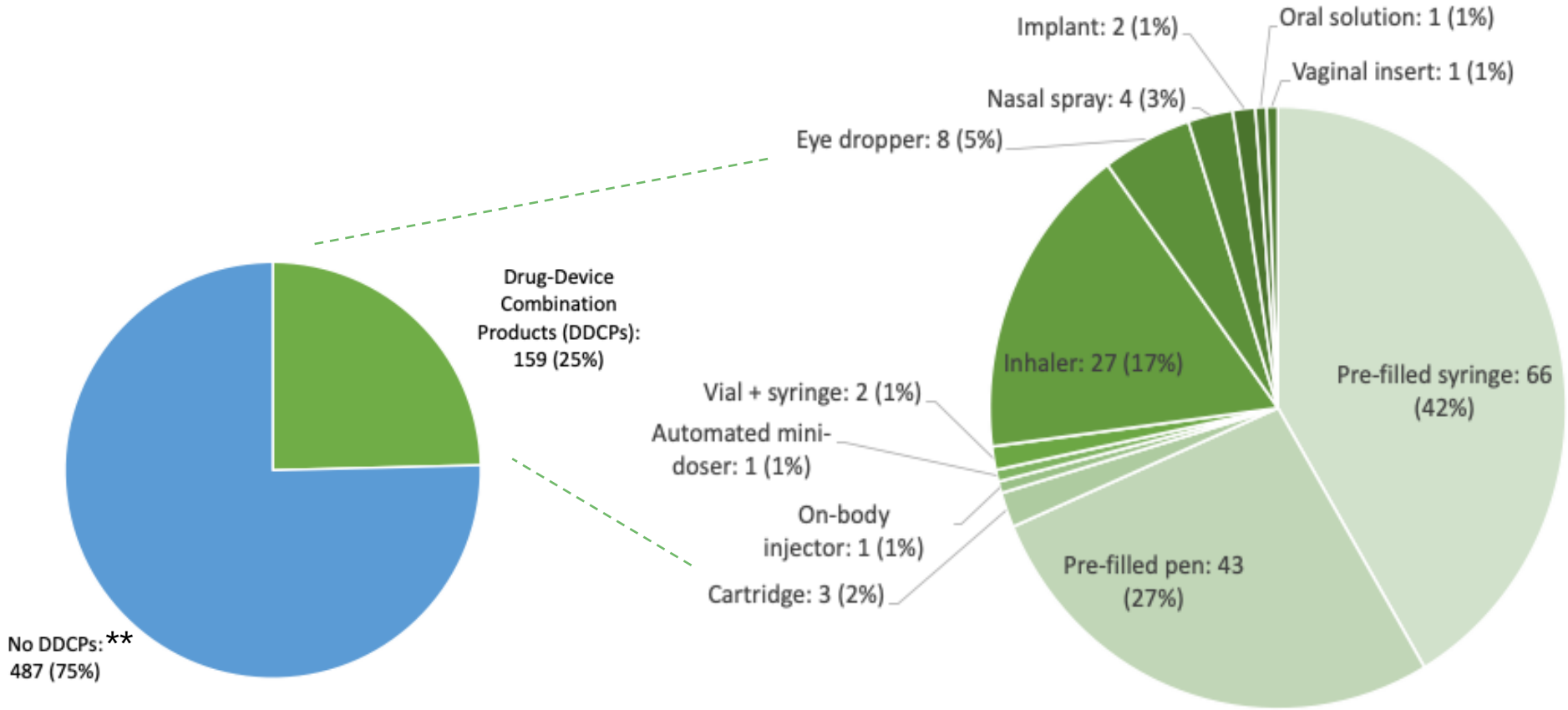
Many global developments on combination product guidelines since 2021



Different terminologies and definitions of (drug-device) combination products exist…

Region	Regulatory term	Scope (combination of …)	Comments
EU (EMA/EC)	No single definition	Drug and device	Initial draft guidance referred to “Drug-device combinations (DDCs)” Later: “medicinal products when used with a medical device”
US (FDA)	Combination Products	Drug, device or biologic	Not necessarily with device
Canada (Health Canada	Drug-Device Combination Products (DDCPs)	Drug and device	
Australia (TGA)	Combination Products	Drug, device or biologic	Biologic example ref to advanced therapies
Japan (PMDA)	Combination Products	Drug, device or processed cell	Ref to advanced therapies
China (NMPA)	Drug-Device Combination Products	Drug and device + Produced as single entity - certain types	“medical products composed of drugs and medical devices and produced as a single entity”
South Korea (MFDS)	Combination Products	(Quasi-) drug and device + Produced as single entity	Quasi-drugs -> cosmetics (incl acne)
Brazil (ANVISA)	No single definition (yet)	Drug (incl. vaccine) and device + Produced as single entity	No regulation available yet

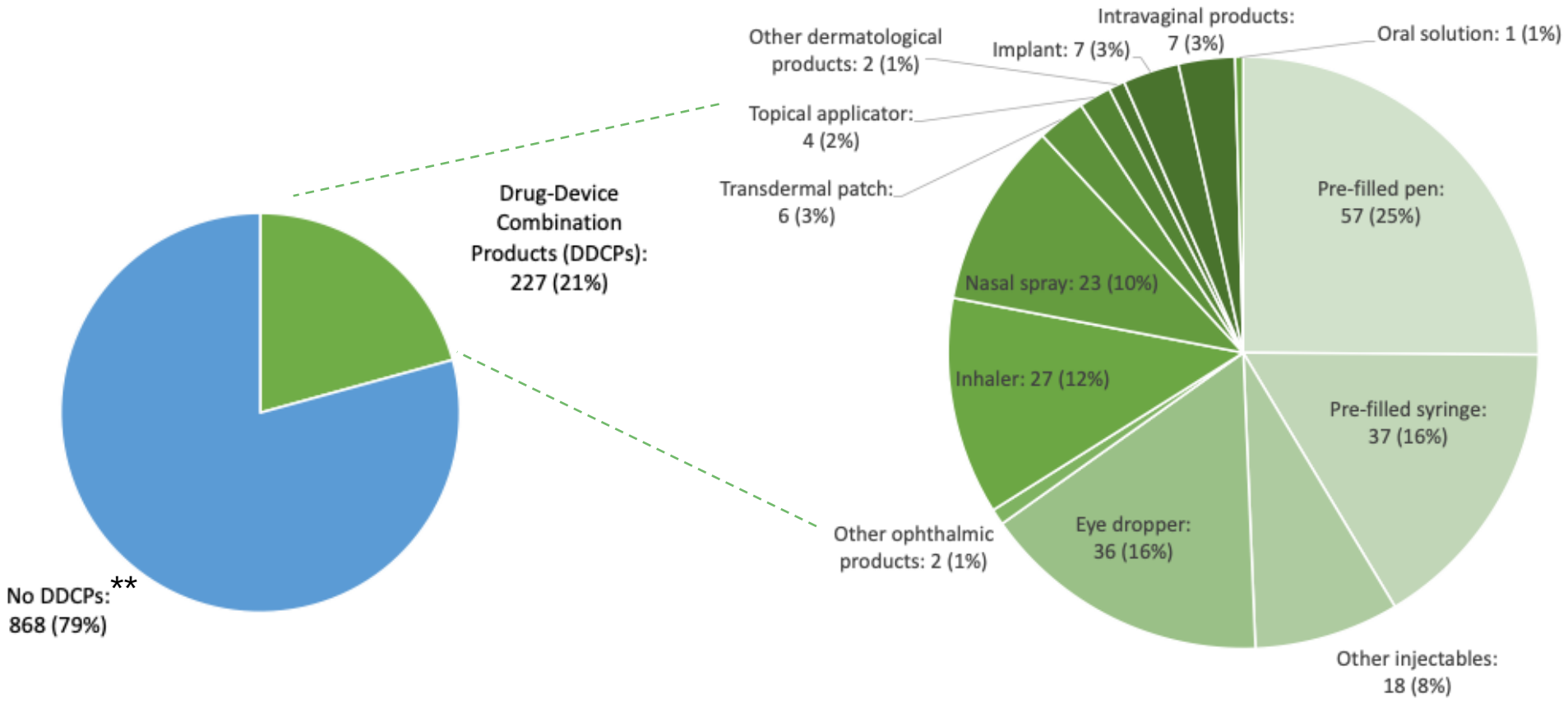
A quarter of EMA approvals in the last ten years are DDCPs*, most relating to injectables and inhalers



*drug is the primary component

**Majority relating to oral products (59%, e.g. tablets and capsules) and IV products provided in vials (33%)

One in five products approved by FDA in the last ten years relate to DDCPs

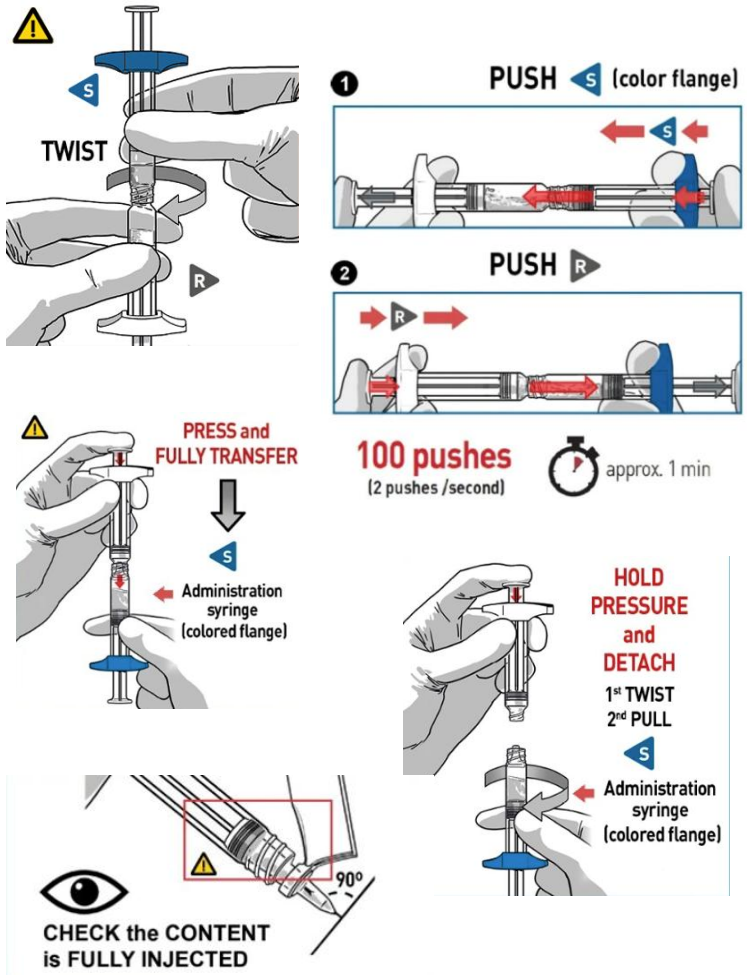


*drug is the primary component

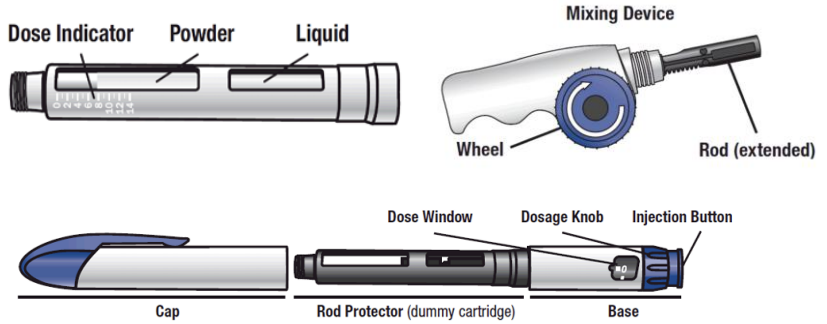
**Majority relating to oral products (45% tablets and capsules) and IV products (39%)

Various types of complex DDCPs identified

Pre-filled syringe of powder and **pre-filled syringe** of solvent

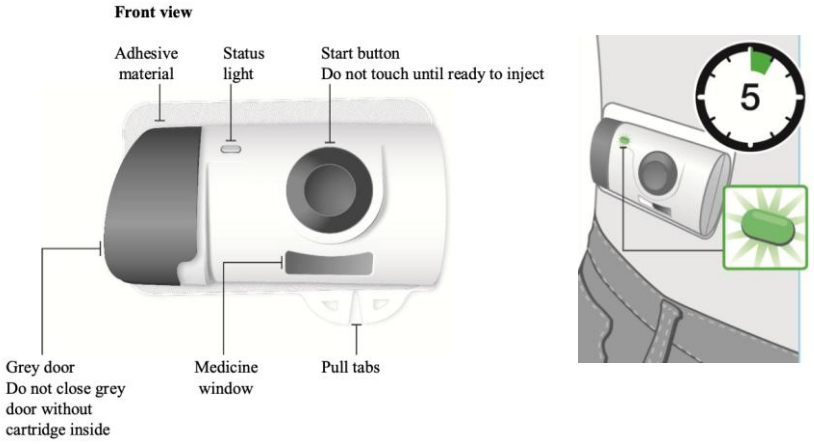


Dual-chamber cartridge with mixing device for use in **autoinjector**

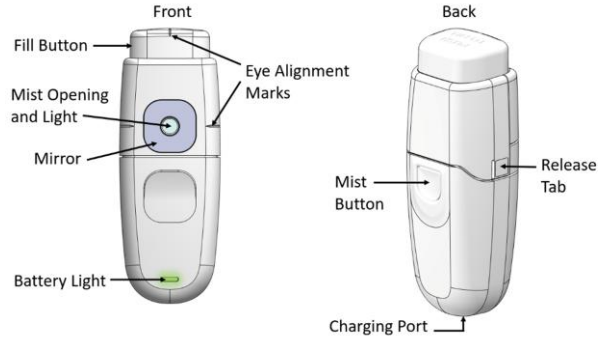


Implant with resorbable and biodegradable component

Cartridge with **on-body injector**



(Electronic) dispenser with ophthalmic spray for topical use



Discussions with companies developing DDCPs

- **General concerns**
  - Globally varying regulations and submission requirements for DDCPs
  - …results in increase of interactions with regulatory authorities, duplication of work etc.
    - Requires more resources from DDCP developers, increases the uncertainty…
- **European Union**
  - Lack of communication between regulators (EMA) and notified bodies (assessment of device)
- **China**
  - Increased uncertainty due to evolving regulations and local registration requirements for devices manufactured in China
  - More clarity needed for transition periods towards new regulations

Recommendations

- **Need for global harmonisation:**
  - Adopt a common terminology (at the global level)
  - Create consistent classification scheme (‘what’s in, what’s out’)
  - Unified standards and submission requirements to reduce regional variations (and potential approval delays)
- **Stimulate regulatory reliance and work-sharing schemes**
- **Endorse early engagement with regulators**
  - E.g. early scientific advice (EMA), with combined advice for drug and device
- **Timing is crucial due to ongoing global developments of guidance documents**

Thank you

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A regulatory perspective for combined ATMPs-Device combination products in Australia

Dr Tony Gill

Director Clinical Evaluation Section 6 (Advanced and Biological Therapies)

Therapeutic Goods Administration

Regulation of advanced therapies in Australia - TGA

We don’t have a dedicated advanced therapies framework in Australia.

Instead, we regulate cell and gene therapies under our biologicals and prescription medicines framework

Advanced Therapies

Biologicals	Gene therapies
Involve **ex-vivo** manipulation of human cells e.g CAR-T cells	Involve **in-vivo** manipulation of human cells
Regulated under the biologicals framework	Regulated under the prescription medicines framework
Section 32 of the Therapeutic goods act	Section 23/24/25 of the Therapeutic goods act

- Different standards apply
- Different GMP requirements
- Different areas of TGA responsible for evaluation

Why regulate ATMPs under different frameworks?

Biological

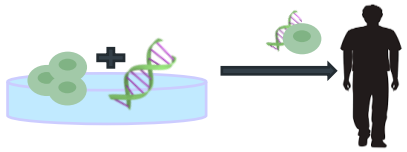
- Regulated under the biologicals framework

Biological medicine

- Regulated under the prescription medicines framework

Advanced Therapies

Cellular therapies



Ex-vivo manipulation / genetic modification

Gene therapies

In-vivo manipulation /genetic modification

Well established frameworks that can be utilised to regulate cell and gene therapies

Different risks

- Starting material=human cells
- Infectious disease safety risk
- Different GMP considerations (contamination)

Regulation of Biologicals

Increasing risks

Class 1 Biologicals

- Low risk
- Notification based scheme
- Post-market review only

Products regulated as class 1 biologicals:
- FMT

Class 2 Biologicals

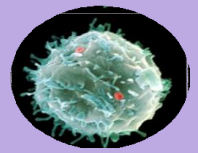
- Low - medium risk
- Must have adequate donor screening
- Minimal manipulation / manufacturing occurs
- Minimal efficacy data needed

Products regulated as class 2 biologicals:
- Corneas
- Skin
- Heart valves
- Bones and tendons
- Amniotic membrane

Class 3 Biologicals

- Medium risk
- Must have adequate donor screening
- Efficacy data needed

Products regulated as class 3 biologicals:
- Some cell therapies e.g mesenchymal stem cells, chondrocytes, T cells (non GM)



Class 4 Biologicals

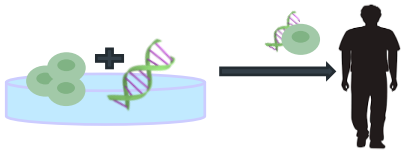
- High risk
- Must have adequate donor screening
- Efficacy data needed
- Product characterisation needed
- Higher level of specifications required

Products regulated as class 4 biologicals:
- CAR T-cells
- Pluripotent stem cells

Advanced Therapies

Product evaluation for ATMPs

Cellular therapies



Ex-vivo manipulation / genetic modification

Regulated under the **biologicals** framework

Cell therapies

Gene therapies

In-vivo manipulation /genetic modification

Regulated under the **medicines** framework
Prescription medicine

Gene therapies

Dossier requirements

Quality | Non-Clinical | Clinical | RMP | GMP

- Different standards apply
- Different GMP requirements
- Different areas of TGA responsible for evaluation

Regulation of combination products

The principal therapeutic effect for the product determines what type of therapeutic good the product is and how it is regulated.

The regulation of combination products may also depend on other factors such as therapeutic claims and intended use mentioned on the product or in advertising.

Commonly:

•medicine - medical device combinations - medical devices that incorporate, or are used to administer a medicine,

•biological – medical device combinations - biologicals presented as a combination product with a medical device component (i.e., integrated with the medical device), such as a a matrix and human cells e.g. chondrocytes

•biological – medicine combinations - biologicals presented as a combination product with a medicine component.

Regulation of combination products

Biological plus medical device – always Biological framework

Medicine, where medicine is plus medical device (i.e. delivery system) – Medicines framework

Medical device incorporating a medicine where medicine is liable to act upon the body with action ancillary to that of the other functions of the medical device e.g. drug-eluting stent – Medical Device framework.

Questions?

www.tga.gov.au

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

PANEL DISCUSSION

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QUESTIONS AND ANSWERS

We encourage you to use the Q&A box to raise questions to the speakers.

If a question you would like to ask has already been raised, you can also “like” that question.

KEY TAKEAWAYS AND INSIGHTS

- For both ATMPs and DDCPs, regulatory frameworks are still developing worldwide.
- For ATMPs: There are ongoing global regulatory harmonization and convergence efforts (WHO, ICH, APEC) to manage the differences in the maturity of frameworks among countries. Opportunities for identifying best practices and development of harmonized guidelines and standards.
- For DDCPs: Lack of common terminology, potential difficulties to classify and navigate different requirements, e.g. for complex devices and drugs.
- Combined ATMPs are complex DDCPs with specific scientific and regulatory challenges (e.g. impact assessment of device to drug effect, biocompatibility, GMP considerations...).
- Need for more global convergence, flexible regulatory pathways based on risk-based approaches and regulatory reliance.
- Importance of early scientific interactions between sponsors/manufacturers and regulators.
- Sharing expertise and best practices among regulators and all stakeholders.

Thank you

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03-06 December 2024

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