



Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Regulatory Perspective of e-Labelling

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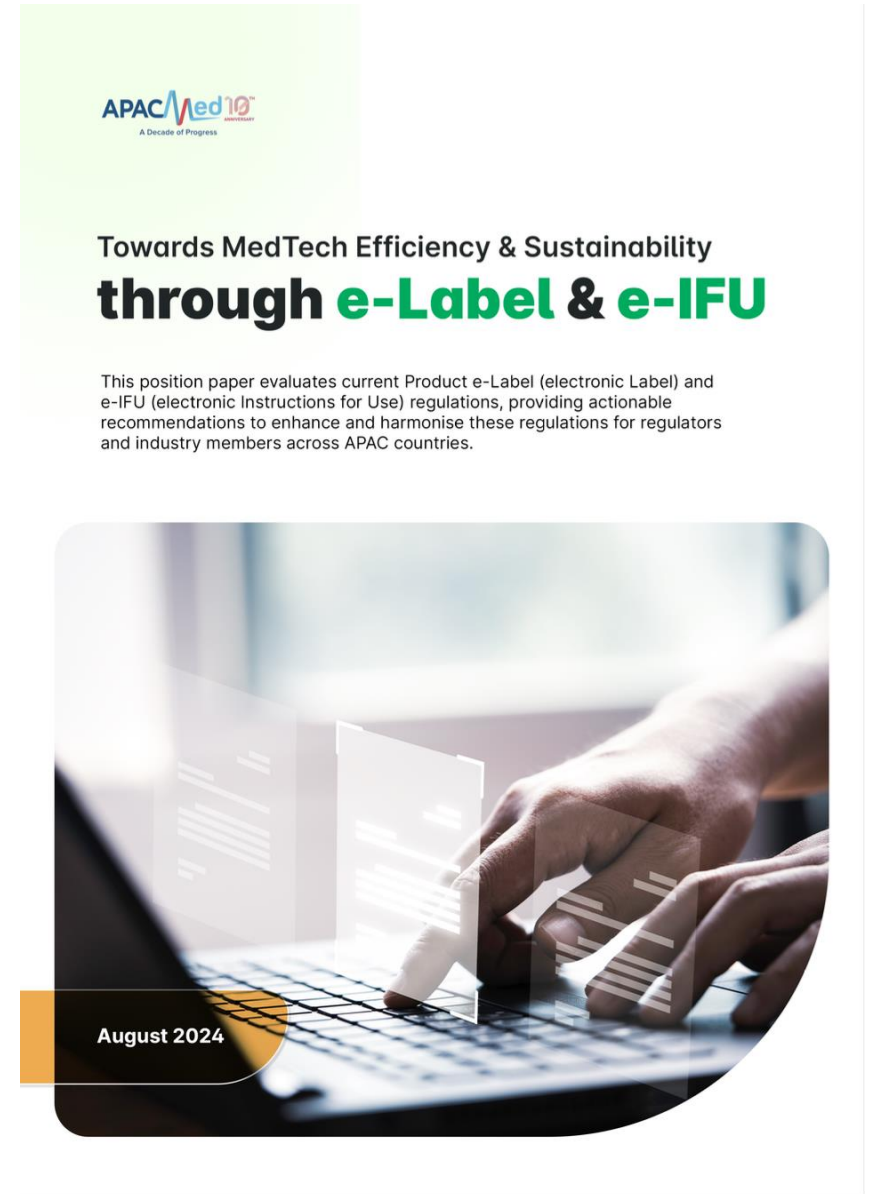
eLabel & eIFU Project Lead (APACMed)

Acknowledgement

The information presented here is derived from the position paper published by APACMed. This paper provides a comprehensive overview of the regulatory landscape, challenges, and recommendations regarding e-Label and e-IFU in the APAC region. It aims to promote dialogue, collaboration, and informed decision-making between industry members and regulators by synthesizing insights from industry experts and companies.



Read the full paper here



Definitions



Label¹: Written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices.

Labelling¹: The label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.

Electronic Labelling¹ (e-Labelling): Any form of labelling content provided in an electronically accessible form supplied by the manufacturer related to a medical device or IVD medical device.

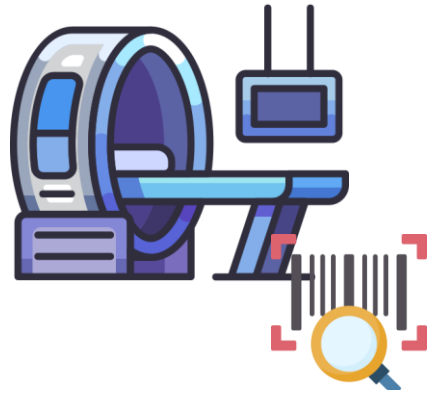
Electronic Instructions for Use (e-IFU)²: Electronic Instructions for Use (e-IFU) refers to instructions displayed in electronic form.

Information Source:

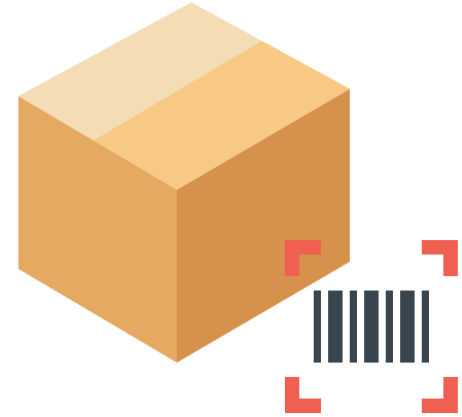
¹ IMDRF (2024). *Principles of Labelling for Medical Devices and IVD Medical Devices*. Retrieved from <https://www.imdrf.org/sites/default/files/2024-04/IMDRF%20GRRP%20WG%20N52%20%28Edition%20%29.pdf>

² GHWP (2023). *Principle of Regulatory Requirements for Electronic Instructions for Use (e-IFU)*. Retrieved from http://www.ahwp.info/sites/default/files/%5BFinal%20version%5D%20GHWP-WG1-WG2-WG3-F002-2023_0.pdf














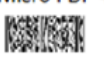
What is e-Label?



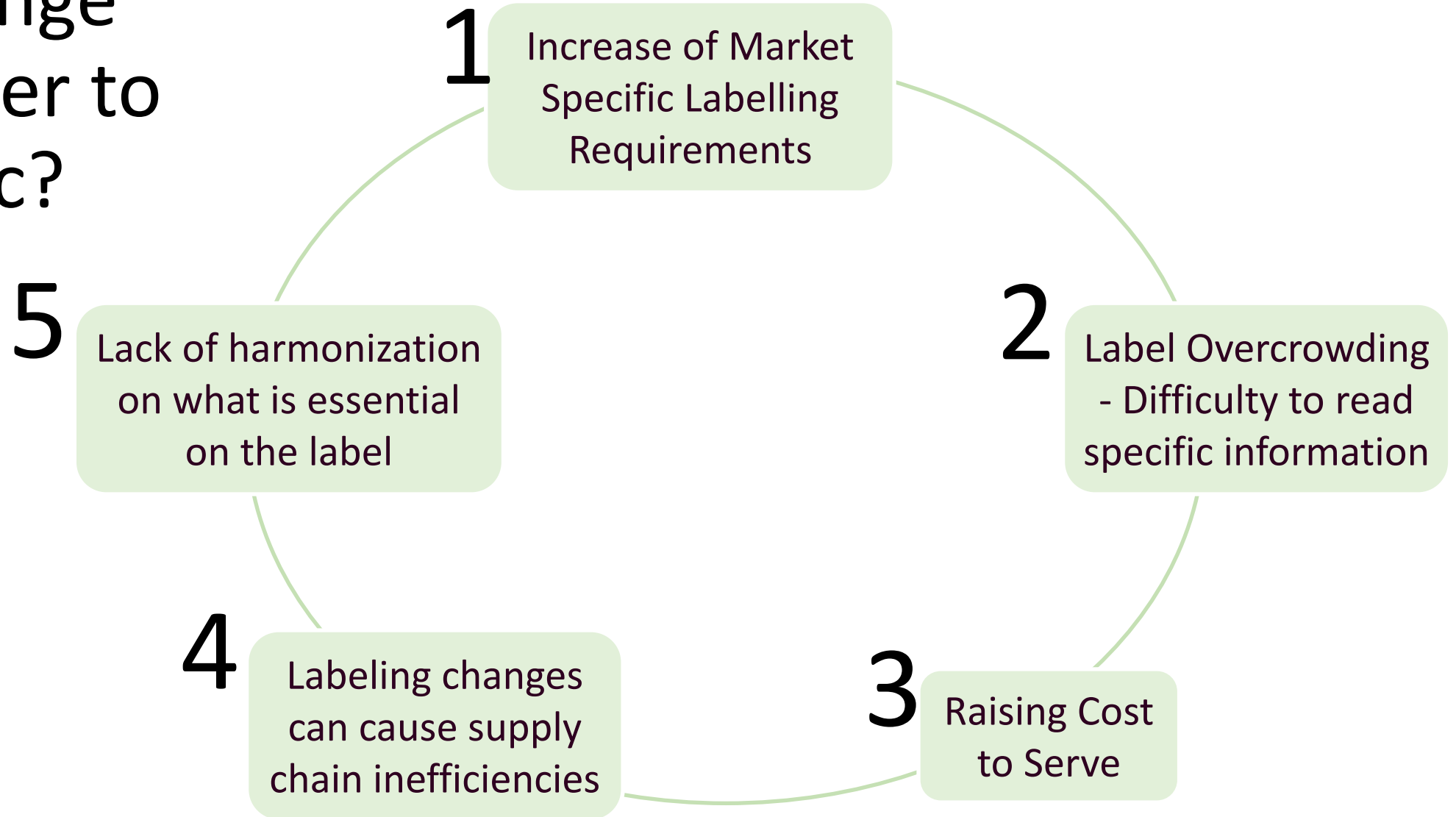
Any form of label content provided in an electronically accessible form supplied by the manufacturer related to a medical device or IVD medical device.



Can come in the form of barcodes, 2D data matrix, RFID, NFC, QR Codes, blockchain, website link

UPC-A & E 	I 2 of 5 (ITF) 	Pharmacode 	QR Code 
EAN-8 & 13 	Cod-a-bar 	Data Matrix 	Micro QR Code 
EAN 128 	Code 39 	PDF-417 	Human Readable  PV000001
Code 128 	GS1-RSS  (01)04512345678906	Micro PDF-417 	

Why Change from Paper to Electronic?




1





Increase of Market Specific Labelling Requirements

General Product Label Information

- Product Name
- Catalog/SKU Number
- Manufacturer Name & Address
- Device Intended Use
- Packaging Information – pack size, contents
- Storage & handling
- Single Use indication (if applicable)
- “STERILE” if the product is sterile (if applicable)
- Expiry date
- Batch/lot/serial No. of the device
- Symbols or words of warning or precautions

Market Specific Labeling Requirements Summary

 Indicates local language is required on the product label

ANZ	China 	Chinese Taipei 	Japan 	Korea 	India
<ul style="list-style-type: none"> • Australian/New Zealand Sponsor name & address 	<ul style="list-style-type: none"> • Registrant/filling agent Information • Production License No. • Registration/filing No. • No. of product technical requirements • Manufacturing date • Shelf Life (not mandatory if there is manufacturing & expiry date) • Authorized Representative Information (for imported devices) • UDI 	<ul style="list-style-type: none"> • License Approval No. • Medical Device Firm Name, Address, and contact information (local representative) • Statement of “The instruction for this product is provided in an electronic version, contact the medical device firm if a paper version is needed”. (If eIFU available) • UDI 	<ul style="list-style-type: none"> • Registration/License Approval No • Approved Product Name • MAH information • Foreign MAH information (if applicable) • D-MAH information (if applicable) • JMDN Name & No. • Device Category • Biological products (if applicable) • JIS T requirements (if applicable) • UDI (GS1-128 code) 	<ul style="list-style-type: none"> • Registration/License Approval No. • Importer Information (if product is imported) • Manufacturing date • Country of Origin • UDI 	<ul style="list-style-type: none"> • Registration/License Approval/Import License No. • Warehouse details/License address • Maximum Retail Price • Customer Care email & phone number • Manufacturing date • Actual/Physical Manufacturer’s address • Month & Year of import (if applicable) • Country of Origin


1

Increase of Market Specific Labelling Requirements

General Product Label Information

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- Single Use indication (if applicable)
- “STERILE” if the product is sterile (if applicable)
- Expiry date
- Batch/lot/serial No. of the device
- Symbols or words of warning or precautions

Market Specific Labeling Requirements Summary

 Indicates local language is required on the product label

Indonesia 	Thailand 	Philippines	Vietnam 	Singapore	Malaysia
<ul style="list-style-type: none"> • Product Registration No. (KEMENKES RI AKL No. XXXXXXXXXXX) • Distribution Center/Distributor information • Importer information 	<ul style="list-style-type: none"> • License Approval/Notification/Listing No. • Importer information • Country of Origin 	<ul style="list-style-type: none"> • Registration No. • Importer information • Distributor information 	<ul style="list-style-type: none"> • Registration No. • License holder Information • Importer information • Manufacturing date • Country of Origin 	<ul style="list-style-type: none"> • UDI (according to implementation phase) 	<ul style="list-style-type: none"> • Registration/License No. • Authorized Representative Information

2

Label Overcrowding - Difficulty to read specific information

Indonesia:

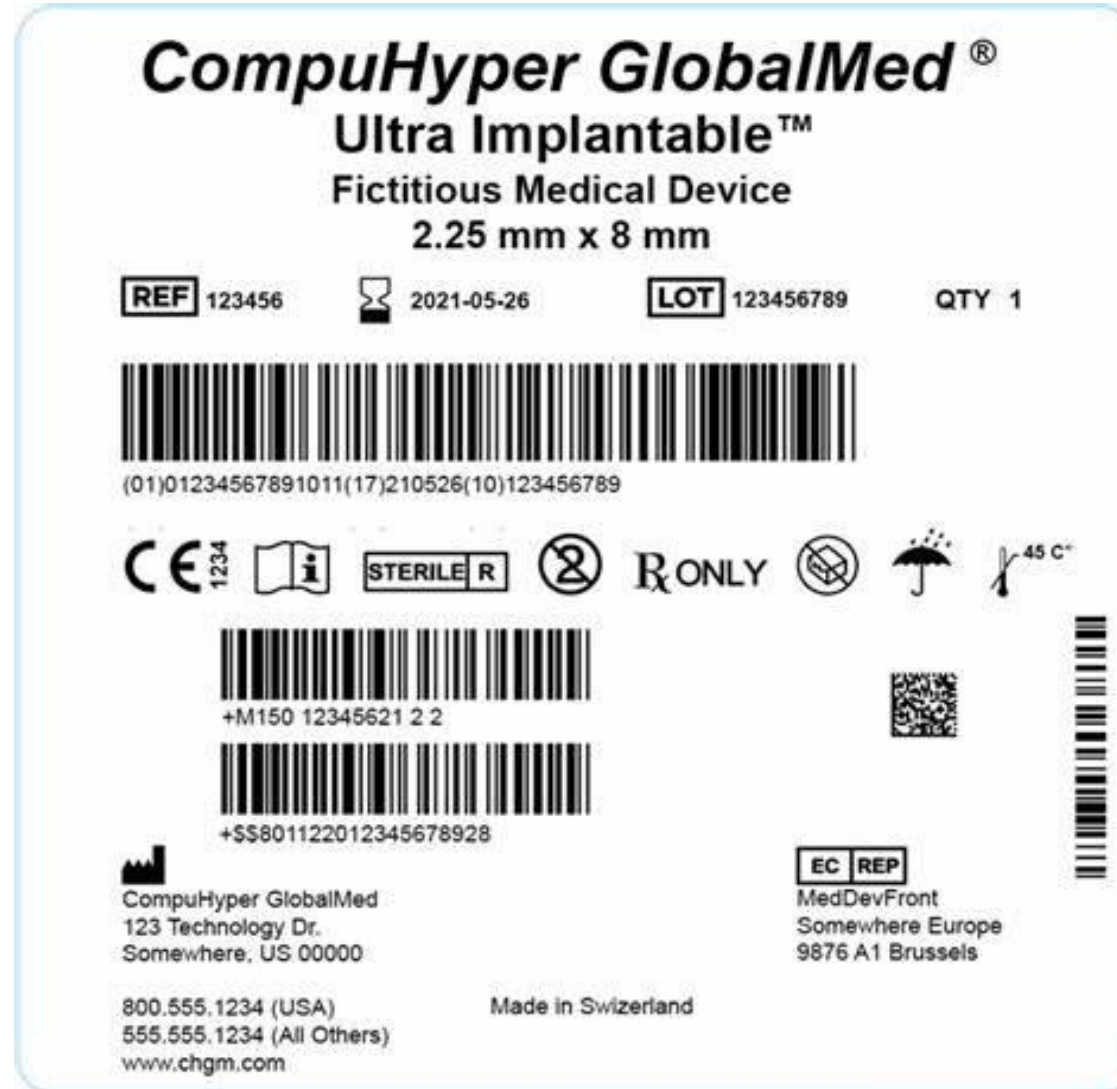
- Product Registration No. (KEMENKES RI AKL No. XXXXXXXXXXX)
- Distribution Center/Distributor information
- Importer information

Thailand:

- License Approval/Notification/Listing No.
- Importer information

Philippines:

- Registration No.
- Importer information
- Distributor information



Vietnam:

- Registration No.
- License holder Information
- Importer information
- Manufacturing date

Malaysia:

- Registration/License No.
- Authorized Representative Information

What are the benefit of e-Labeling?

1



Reduction of Labels & IFUs being Physically Misplaced or Destroyed due to Human Errors

2



Ease & Speed of Updates

3



Inclusion of Multimedia Content

4



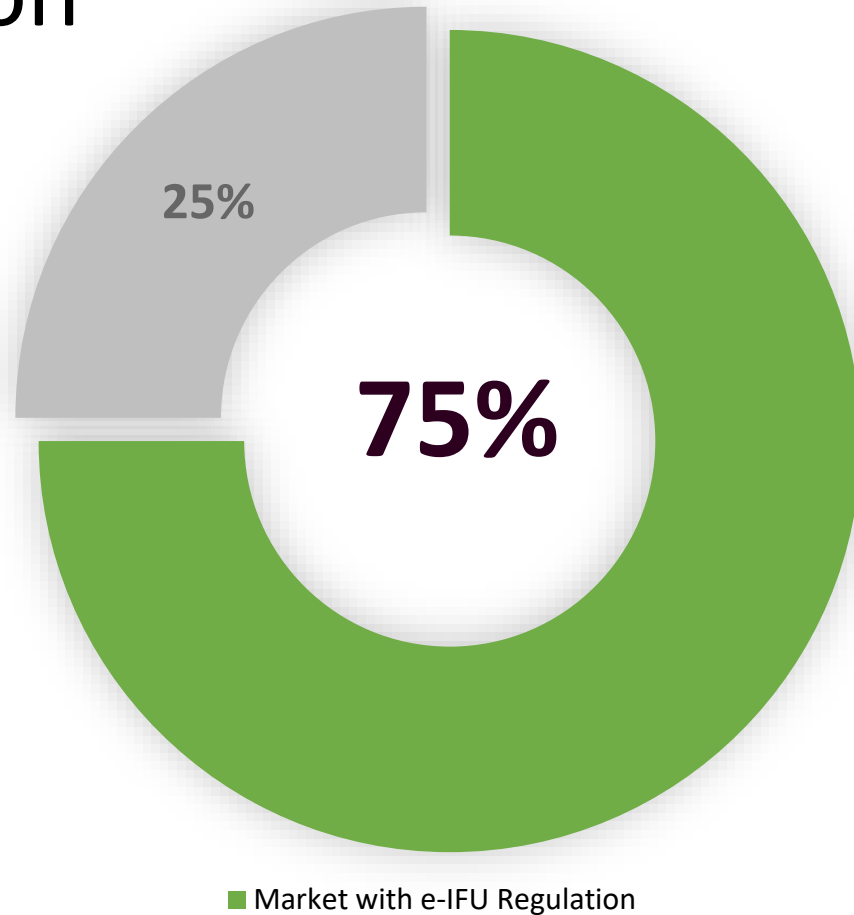
Reduce Environmental Impact

5



Ensure Patient Safety and Compliance

In APAC, how is the MedTech Industry progressing on Electronic Solutions?



There is no e-Label regulation for medical device at the moment.

55%

of the current e-IFU Regulations allow Professional Use while only 45% of them cover both professional & home use devices.

71%

of our respondents stated their organisation has implemented e-IFU solutions for their products.

APAC Medical Device e-IFU Regulation Overview

Market	Medical Device e-IFU Regulation in Place?	Regulation Covers Professional Use, Home Use, or Both?	Who owns & maintains the e-IFU database?	Does change from paper IFU to e-IFU require notification/Change Submission?
Australia*	Yes	Professional Use and consumers for standalone software	Manufacturers	Yes
China	No	NA	NA	NA
Chinese Taipei	Yes	Professional Use	Manufacturers	No
Japan	Yes	Professional Use	Health Authority	Yes
South Korea	Yes	Both**	Manufacturers	Yes
India	Yes	Both	Manufacturers	Yes
Indonesia	No	NA	NA	NA
Thailand	Yes	Both	Manufacturers	Yes
Philippines	No	NA	NA	NA
Vietnam	Yes	Both	Manufacturers	Yes
Singapore	Yes	Professional Use	Manufacturers	Yes
Malaysia	Yes	Professional Use	Manufacturers	Yes

* At the time of writing this paper, the TGA is seeking feedback on the availability of e-IFU for a greater range of medical devices including consumer goods.

** At the time of writing, most medical device categories are eligible for e-IFU adoption. Refer to "Notification No. 2024-18, March 27, 2024" for the full list. As per Article 2 (Designation Scope) Clause (1), devices listed in the Appendix, regardless of use environment, can provide IFUs on the manufacturer's website.

APAC Medical Device e-IFU Regulation Overview

Group 1:
5 markets allow eIFU for Professional Use Devices

Market	Medical Device e-IFU Regulation in Place?	Regulation Covers Professional Use, Home Use, or Both?	Who owns & maintains the e-IFU database?	Does change from paper IFU to e-IFU require notification/Change Submission?
Australia*	Yes	Professional Use and consumers for standalone software	Manufacturers	Yes
China	No	NA	NA	NA
Chinese Taipei	Yes	Professional Use	Manufacturers	No
Japan	Yes	Professional Use	Health Authority	Yes
South Korea	Yes	Both**	Manufacturers	Yes
India	Yes	Both	Manufacturers	Yes
Indonesia	No	NA	NA	NA
Thailand	Yes	Both	Manufacturers	Yes
Philippines	No	NA	NA	NA
Vietnam	Yes	Both	Manufacturers	Yes
Singapore	Yes	Professional Use	Manufacturers	Yes
Malaysia	Yes	Professional Use	Manufacturers	Yes

* At the time of writing this paper, the TGA is seeking feedback on the availability of e-IFU for a greater range of medical devices including consumer goods.

** At the time of writing, most medical device categories are eligible for e-IFU adoption. Refer to "Notification No. 2024-18, March 27, 2024" for the full list. As per Article 2 (Designation Scope) Clause (1), devices listed in the Appendix, regardless of use environment, can provide IFUs on the manufacturer's website.

APAC Medical Device e-IFU Regulation Overview

Group 2:
4 markets allow eIFU for Professional Use & Home Use/Consumer Devices

Market	Medical Device e-IFU Regulation in Place?	Regulation Covers Professional Use, Home Use, or Both?	Who owns & maintains the e-IFU database?	Does change from paper IFU to e-IFU require notification/Change Submission?
Australia*	Yes	Professional Use and consumers for standalone software	Manufacturers	Yes
China	No	NA	NA	NA
Chinese Taipei	Yes	Professional Use	Manufacturers	No
Japan	Yes	Professional Use	Health Authority	Yes
South Korea	Yes	Both**	Manufacturers	Yes
India	Yes	Both	Manufacturers	Yes
Indonesia	No	NA	NA	NA
Thailand	Yes	Both	Manufacturers	Yes
Philippines	No	NA	NA	NA
Vietnam	Yes	Both	Manufacturers	Yes
Singapore	Yes	Professional Use	Manufacturers	Yes
Malaysia	Yes	Professional Use	Manufacturers	Yes

* At the time of writing this paper, the TGA is seeking feedback on the availability of e-IFU for a greater range of medical devices including consumer goods.

** At the time of writing, most medical device categories are eligible for e-IFU adoption. Refer to "Notification No. 2024-18, March 27, 2024" for the full list. As per Article 2 (Designation Scope) Clause (1), devices listed in the Appendix, regardless of use environment, can provide IFUs on the manufacturer's website.

APAC Medical Device e-IFU Regulation Overview

Group 3:
3 markets do not have eIFU Regulation

Market	Medical Device e-IFU Regulation in Place?	Regulation Covers Professional Use, Home Use, or Both?	Who owns & maintains the e-IFU database?	Does change from paper IFU to e-IFU require notification/Change Submission?
Australia*	Yes	Professional Use and consumers for standalone software	Manufacturers	Yes
China	No	NA	NA	NA
Chinese Taipei	Yes	Professional Use	Manufacturers	No
Japan	Yes	Professional Use	Health Authority	Yes
South Korea	Yes	Both**	Manufacturers	Yes
India	Yes	Both	Manufacturers	Yes
Indonesia	No	NA	NA	NA
Thailand	Yes	Both	Manufacturers	Yes
Philippines	No	NA	NA	NA
Vietnam	Yes	Both	Manufacturers	Yes
Singapore	Yes	Professional Use	Manufacturers	Yes
Malaysia	Yes	Professional Use	Manufacturers	Yes

* At the time of writing this paper, the TGA is seeking feedback on the availability of e-IFU for a greater range of medical devices including consumer goods.

** At the time of writing, most medical device categories are eligible for e-IFU adoption. Refer to "Notification No. 2024-18, March 27, 2024" for the full list. As per Article 2 (Designation Scope) Clause (1), devices listed in the Appendix, regardless of use environment, can provide IFUs on the manufacturer's website.

In APAC, how is the Pharma Industry progressing on Electronic Solutions?

	Labelling availability on RA website	Easy accessibility to e-label (e.g., via bar code)	Structured contents of labelling such as XML	Eliminating paper labelling from a commercial pack	Interoperable e-labelling
EU	√	In Discussion	In Discussion		In Discussion
Japan	√	√	√	√	
US	√		√		√
Singapore	√	Voluntary		Voluntary	
Chinese Taipei	√	√	Pilot underway	Pilot underway	
South Korea	√	In Discussion	√	In Discussion	
Malaysia	√	In Discussion		Pilot underway	
China	Some Products				

Global e-Labeling Implementation Status in Pharma sector extracted from APAC e-Labeling EWG Position Paper 2023

Partnerships



Active collaboration among stakeholders, consistent oversight, and a commitment to ongoing improvement are essential for the successful implementation of e-Labeling for MedTech Industry.

Thank you!