APACMed 10TH ANNIVERSARY
A Decade of Progress

Towards MedTech Efficiency & Sustainability

through e-Label & e-IFU

This position paper evaluates current Product e-Label (electronic Label) and e-IFU (electronic Instructions for Use) regulations, providing actionable recommendations to enhance and harmonise these regulations for regulators and industry members across APAC countries.

Table of Contents

Terms & Definitions

To maintain consistency, the terminology and definitions that are employed extensively in the position paper are provided as follows for clarity and uniformity:

01 Label: 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.

02 Electronic Label (e-Label) or Digital 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.

03 Labelling[1]: 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.

NOTE 1: Labelling can also be referred to as "information supplied by the manufacturer."
NOTE 2: Labelling can be in printed or electronic format and may either physically accompany the medical device or direct the user to where the labelling information can be accessed (such as through a website), as permitted by regulatory jurisdiction.

04 Electronic Labelling[1] (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.

05 Instructions for Use[1]: General and technical information provided by the manufacturer to inform the user of the medical device or IVD medical device's intended purpose and proper use and of any contraindications, warnings, or precautions to be taken. It is provided by the manufacturer to support and assist the device users in its safe and appropriate use.

NOTE: Instructions for use can also be referred to as "package insert."

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

- by the device ("help" system, or graphical user interface (GUI)-based dialogues),
- contained in portable electronic storage media supplied by the manufacturer together with the device, or
- online, through the manufacturer's website. (TGA # D18-10786654)

NOTE 1: Instructions for use (IFU) may be referred to other terms. Examples are "package insert", "directions for use", "User Manual", "Technical Manual".
NOTE 2: The e-IFU must be a complete representation of all the information required to be included in the IFU as specified in the regulations or requirements of the applied jurisdiction.

07 Home Use or Consumer Medical Device: A device that is used by a lay user[1], who does not have formal training in a relevant field or discipline.

Executive Summary

In an era marked by rapid digital transformation and technological advancements, the adoption of electronic label (e-Label) and electronic Instructions for Use (e-IFU) signifies a move towards greater efficiency, sustainability, and improved user experience. The medical device sector is at the forefront of this change, particularly with the integration of e-Labels and e-IFUs. However, industry members and regulators in the APAC region are confronted with challenges as they navigate the intricate regulatory landscape, while attempting to capitalise on the benefits electronic solutions have to offer.

This position paper provides a comprehensive overview of the regulatory landscape, challenges, and recommendations regarding e-Label and e-IFU in the APAC region. APACMed aims to foster dialogues, collaboration, and informed decision-making between industry members and regulators on the topic by synthesising insights from industry experts and companies.

In order to have a holistic view of the regulatory landscape and operational challenges associated with implementing e-Label and e-IFU in the medical device industry, APACMed launched a detailed survey targeting its members. The survey comprised a series of carefully designed questionnaires aimed at gathering insights on various aspects of e-Label and e-IFU. These questionnaires covered topics such as regulatory requirements, adoption readiness, benefits and risks. The collected data were analysed to identify prevailing trends and common challenges. This robust methodological approach ensures that the conclusions drawn were well-founded and reflective of the collective experiences and perspectives of APACMed members.

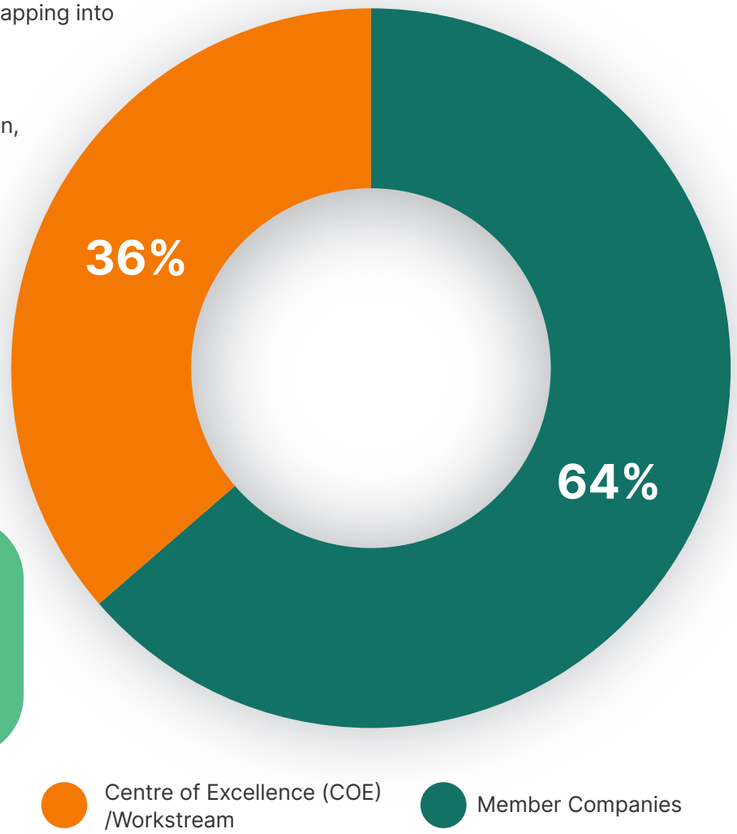
Our analysis has shown a diverse regulatory environment characterised by differing requirements across various jurisdictions. This fragmentation poses challenges for industry members seeking to comply with the regulations while tapping into the benefits of electronic solutions.

To address these challenges and maximise the potential of e-Label and e-IFU in the region, APACMed proposes a series of actionable recommendations that focus on harmonising regulations, fostering collaboration, and enhancing regulatory clarity and guidance.

The data presented in this position paper is a collective effort of APACMed Market Centres of Excellence (COE) / workstreams, its member companies and local industry associations.

CoE/Workstreams: Sub-region or country team that is responsible for assessing the topic from country regulation perspectives.

Member Companies: Participants from the medical device industry who shared their challenges and recommendations for e-Label and e-IFU.



Introduction

Asia Pacific (APAC) represents a unique set of challenges in the management of paper labels and Instructions for Use in the medical device industry. This diverse region is comprised of numerous countries, each with distinct regulatory requirements and official languages. The complexity arising from these variations requires precise compliance measures, accurate translations, and efficient logistics management. At the same time, manufacturers face increased costs to serve in fulfilling their obligations.

A significant issue is the proliferation of country-specific labelling requirements, which leads to label overcrowding. This overcrowding often results in difficulties for healthcare professionals and patients in reading and understanding essential information. Labelling changes, necessitated by evolving regulations, can cause substantial inefficiencies in supply chain agility, potentially leading to product shortages. Furthermore, the lack of harmonisation on what constitutes essential information on product labels across different countries compounds these challenges.

One promising solution to these challenges is the transition from paper to e-Label and e-IFU. Across the APAC region, this shift is not merely a technological upgrade but a strategic response to evolving consumer expectations. The growing penetration of digital devices and connectivity in APAC underscores the relevance of e-Label and e-IFU. Consumers are increasingly expecting intuitive, interactive product information that is accessible anytime, anywhere. This digital transformation not only fulfils these expectations but also aligns with global trends towards sustainability and operational efficiency. The benefits of this transition will be elaborated in the advantages section of this position paper.

The objective of this position paper is to provide a comprehensive overview of the product labelling regulatory requirements across APAC markets, with an emphasis on the challenges associated with managing paper labels and IFUs. It aims to offer strategic recommendations for both industry stakeholders and regulators regarding electronic solutions, with the goal of streamlining processes, enhancing compliance, and ultimately improving patient safety and device usability. Through this collaborative approach, APACMed aspires to foster a more harmonised regulatory environment that supports innovation and efficiency within the medical device industry.

In this position paper, we begin by outlining the challenges inherent in managing paper product labels. Following this, we explore the advantages of digital alternatives, which may serve as a viable solution to these issues. We then provide a detailed overview of the regulatory framework governing medical device e-Labels and e-IFUs. The paper concludes with a set of practical recommendations to drive MedTech efficiency and sustainability through e-Label and e-IFU.

Paper Product Label Management

To further illustrate the complexity and diversity of label requirements across the APAC region, we have compiled a comprehensive comparison table to provide an overview of the market-specific regulatory requirements for medical device product labels in key markets within the region, in addition to general product label information. By examining this table, you will gain a clearer understanding of the vast differences in product label obligations that manufacturers have to comply with. These varying requirements present significant challenges, from ensuring accurate translations to meeting country specific regulatory requirements, all of which contribute to the delayed introduction of new medical technologies, increased operational burden and costs. The following table highlights these diverse requirements, underscoring the critical need for harmonisation and streamlined processes in the industry.

General Product Label Information

The following information is generally required by APAC markets for Product Label:

- Product Name
- Catalogue/SKU Number
- Manufacturer Name & Address
- Device Intended Use
- Packaging Information – pack size, contents
- Storage and handling
- Single Use indication (if applicable)
- "STERILE" if the product is sterile (if applicable)
- Expiry date
- Batch/lot/serial number of the device
- Symbols or words of warning or precautions

The following table summarises market-specific product label requirements in addition to the general product label information listed above:

The symbol indicates that the market requires local language (other than English) on product labels.

Markets	Market Specific Product Label Requirements
Australia/ New Zealand	• Australian/New Zealand Sponsor name and address
China Simplified Chinese	• Registrant/filing agent Information • Production License number (for local made devices) • Registration/filing number • Number of product technical requirements • Manufacturing date • Shelf Life (not mandatory if there is a manufacturing & expiry date) • Authorised Representative Information (for imported devices) • Unique Device Identification (UDI)
Chinese Taipei Traditional Chinese	• License Approval Number • 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 e-IFU available) • UDI

Markets	Market Specific Product Label Requirements
India	• Registration/License Approval/Import License number • 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
Indonesia Bahasa Indonesia	• Product Registration number (KEMENKES RI AKL No. XXXXXXXXXX) • Distribution Centre/Distributor information • Importer information
Japan Japanese	• Registration/License Approval Number • Approved Product Name • Marketing Authorisation Holder (MAH) information • Foreign MAH information (if applicable) • Designated Marketing Authorisation Holder (DMAH) information (if applicable) • Japanese Medical Device Nomenclature (JMDN) Name & Number • Device Category • Biological products (if applicable) • Japanese Industrial Standards - Technology (JIS T) requirements (if applicable) • UDI (GS1-128 code)
South Korea Korean	• Registration/License Approval Number • Importer Information (if product is imported) • Manufacturing date • Country of Origin • UDI
Malaysia	• Registration/License Number • Authorised Representative Information
Philippines	• Registration number • Importer information • Distributor information
Singapore	• UDI (according to implementation phase[3])
Thailand Thai	• License Approval/Notification/Listing Number • Importer information • Country of Origin
Vietnam Vietnamese	• Registration/License number • License holder Information • Importer information • Manufacturing date • Country of Origin

Table 1: Summary of Market Specific Labelling Requirements

Challenges

Below highlights the challenges associated with the maintenance of paper product labels and IFUs. This critical analysis highlights the obstacles and inefficiencies that come with conventional labelling methods, emphasising the need for digital alternatives.

Global SKUs & Local Requirements

Managing global Stock Keeping Units (SKUs) with multiple local specific labelling requirements poses a significant challenge. The challenge arises from the need to incorporate diverse regulatory requirements onto a single label, resulting in overcrowding and making it difficult to present the information clearly. This complexity not only increases the possibility of human errors, but it also decreases product supply agility. Manufacturers are required to revise product labels to comply with evolving requirements, leading to delays and inefficiencies in product distribution.

Version Control

Ensuring the correct version of paper-based product labels and IFUs is supplied consistently presents another major challenge. This is exacerbated by limited visibility into how local distributors manage version changes. Manufacturers have to invest in rigorous version control processes to prevent the distribution of incorrect or outdated product labels and IFUs, which can compromise regulatory compliance and patient safety. Additionally, maintaining inventory and managing the disposal of outdated labels and IFUs when updates occur not only impact the efficient delivery of cost-effective devices, but also have a significantly negative impact on the environment.

Lack of Harmonised Approach

The lack of a harmonised approach to essential label information further complicates the matters. Different countries mandate specific labelling requirements, creating a fragmented regulatory landscape. This forces the manufacturers to customise labels and IFUs for each market, which increases the risk of errors and inconsistencies, and ultimately affects the usability and safety of medical devices.

Resource Intensive Exercise

The overall management of paper labels and IFUs is a resource-intensive task that significantly increases the cost-to-serve. From the initial design to printing, distribution, ongoing updates and relabeling processes, each step demands substantial human & financial resources. These efforts cumulatively result in higher operational costs and strain on manufacturers, potentially affecting their ability to deliver cost-effective and timely medical devices to the market.

Label Printing Quality & Consistency

Maintaining high standards of paper label and IFU printing quality and consistency is crucial. Labels must display content using high-quality materials and ink to ensure they stay legible and intact throughout the product's lifecycle. Degradation in label quality can result in loss of critical information, posing safety risks and risking regulatory non-compliance.

Local Labelling Rework

Often, product labels and IFUs require rework at local warehouses to meet specific local language and regulatory requirements. This step not only delays the time-to-market but also introduces potential errors during the relabelling process. Ensuring local adaptations are accurate and comply with regulation requirements adds a layer of complexity to the supply chain when providing paper labels & IFUs.

Advantages of Electronic Labelling Solutions

The advantages of electronic solutions for medical device product labels and IFUs include:

01 **Reduction of Labels & IFUs Misplaced or Destroyed due to Human Errors:**
Electronic solutions significantly reduce the risk of labels and IFUs being physically misplaced, damaged, or destroyed. e-Label and e-IFU can be presented in three distinct forms: online, through a centralised database or website, portable media (e.g.: USB, CD, etc.) or fitted with a built-in system visually displaying the instructions for use in the medical device. The multifaceted approach significantly reduces the risks associated with the misplacement or destruction of labels and IFUs, ensuring they are safeguarded against the vulnerabilities of physical documents that may be lost, damaged, or improperly handled due to human error. e-Label & e-IFU access can be on various devices, such as smartphones, tablets, and computers; making it easier for the users to retrieve information when needed. This feature is particularly beneficial in healthcare settings, where quick access to accurate information is critical.

02 **Ease and Speed of Updates:**
e-Label and e-IFU can be updated quickly and easily, ensuring the most current information is always available to users. This capability allows manufacturers to respond promptly to regulatory changes, product modifications, or safety updates; thereby enhancing compliance and minimising the risk of outdated information being used. The ability to make instant updates increases supply chain agility by reducing the time and effort required to implement changes. This allows products to reach the market faster and adapt more swiftly to regulatory or market demands, without the need for costly and time-consuming reprinting of paper product labels or IFUs. e-Label and e-IFU support innovation by accommodating more rapid updates to the product labels and IFUs as digital health advances.

03 **Inclusion of Multimedia Content:**
In research conducted by BI&T, it is shown that only 46% of individuals skim through the instructional materials, and 35% use them only as a reference without fully engaging with the content[4]. Unlike conventional paper product labels and IFUs, e-Label and e-IFU can incorporate multimedia elements such as training videos, interactive diagrams, and audio instructions. Features like the search function allow users to quickly find keywords, saving time and improving efficiency and access to critical information. This enriches the user experience by providing more comprehensive and engaging information, which can improve understanding and adherence to instructions, ultimately enhancing patient safety and device efficacy.

04 **Environmental Impact Reduction:**
Transitioning to e-Labels and e-IFUs offers significant environmental advantages by reducing paper production, printing, and distribution. This transition minimises paper consumption, reduces the carbon footprint from transportation and printing, and cuts down on landfill waste. Schehlein et al summarised that transitioning from paper to e-IFU would help reduce waste and carbon emissions during ophthalmic surgery[5,6]. Opting for electronic over paper labels and IFUs can also help reduce Ethylene Oxide (EtO) emissions, contributing to environmental safety. The inclusion of paper IFU in the sterile device package increases EtO usage because paper IFU absorbs EtO. Increasing the use of e-Label and e-IFU can therefore help reduce EtO emissions. As electronic labels and IFU can be shared digitally, it eliminates the need for physical shipping and storage of paper-based materials. Adopting e-Labels and eIFUs is also aligned with the WHO's vision to accelerate digital health transformations as outlined in the "Global Strategy on Digital Health 2020-2025"[7], along with other digital systems in the future.

05 **Harmonisation With International Regulatory Requirements:**
Harmonising regulatory requirements for e-Labels and e-IFUs is crucial to ensure that healthcare professionals and patients worldwide have access to consistent and accurate product information. This harmonisation is not just a matter of regulatory compliance but also a strategic step towards global healthcare standardisation. By aligning e-Label and e-IFU regulatory requirements, we can eliminate the discrepancies and confusion stemming from varied regional requirements. This leads to a streamlined process for healthcare professionals and patients to access essential information, reducing the risk of errors, and enhancing patient safety. Ultimately, such harmonisation cultivates trust & reliability in medical products and services, contributing to the overall enhancement of global healthcare systems.

06 **Ensuring Patient Safety & Compliance:**
e-IFU provides assurance to healthcare practitioners and end users that medical devices with extended shelf life or use spans are used with the latest instructions. Given that the majority of the medical devices on the market have a long shelf life, it is crucial that the IFUs keep pace with any revisions that may occur.
The revisions could stem from regulatory changes, the emergence of new safety information, or modifications to usage guidelines. The reliance on paper IFUs heightens the risk of these devices being accompanied by outdated information, which could lead to safety concerns and non-compliance with the latest regulations. By adopting e-IFUs, the industry could play a vital role in ensuring that every device is used with the latest instructions, thereby safeguarding patient safety.

07 **Integration with other Systems:**
Electronic labelling can be integrated with other digital platforms, such as inventory management, supply chain, and regulatory compliance systems. This integration streamlines operations and supports comprehensive management of the entire product lifecycle.

In summary, electronic labelling addresses the challenges of paper product labels and IFUs by accelerating time-to-market, enhancing flexibility, increasing agility in regulatory compliance, improving supply chain efficiency, and reducing operation costs across diverse regulatory requirements.

While APACMed recognises the numerous advantages of electronic solutions for product labels and IFU, we are also aware of the practical challenges associated with its implementation. Some of these challenges, which are longstanding and not new to the industry, are outlined below. Nonetheless, there are viable solutions that merit consideration and exploration by stakeholders (health authorities, local governments, manufacturers, healthcare practitioners, and end users). Active collaboration among stakeholders' on consistent oversight, and a commitment to ongoing improvement are essential for the successful resolution of these challenges.

Challenges	Potential Solutions
Barriers to accessing digital technologies and information.	A multi-pronged approach to address inadequate digital literacy skills or limited access to digital information among certain consumers:
Some consumers, particularly those in older demographics or in regions with limited digital literacy, may have inadequate digital skills or limited access to digital information and struggle with the transition from conventional printed labelling to electronic formats.	The approach involves maintaining a dual system of both conventional printed physical labelling and electronic labelling for a transitional period. It includes implementing educational programs to enhance digital literacy among end users with limited digital literacy skills, establishing partnerships with local community centres and organisations to provide hands-on assistance and training, and improving digital infrastructure in regions with limited access to digital information. Additionally, a paper version can be requested if needed.
Technology Integration and Connectivity Issues	A hybrid approach to overcome the barriers associated with the use of e-IFUs that rely on technology like apps, QR codes, or online platforms:
e-IFUs often rely on technology like apps, QR codes, or online platforms, which present barriers for users who lack compatible devices or proficiency in using them. Additionally, poor network connectivity can impact the accessibility of e-IFUs, especially in regions or healthcare settings with limited internet access.	The approach involves the use of both digital and physical copies of instructions. Physical copies are provided for users who lack compatible devices or proficiency in using them. Manufacturers can simultaneously develop offline solutions, such as pre-loaded tablets or USB drives with all necessary instructions and information. They can also conduct training sessions to enhance users' proficiency in using digital devices and accessing e-IFUs, and explore partnerships with telecommunication companies to improve network connectivity in underserved areas.

Regulatory Landscape – e-Label

The COVID-19 pandemic has accelerated the shift towards digital solutions, including e-Labelling, in the healthcare and pharmaceutical sectors globally. Based on the APACMed e-Label and e-IFU survey, we have confirmed that there is no established e-Label regulation for medical devices in the region. Research findings[8] indicate that e-Label efforts in the pharmaceutical field are at varying stages of development across Asia (shown in Table 2 below), with most markets initiating discussions on the topic. The diversity of approaches in the region presents challenges and suggests the need for regional guidelines to streamline and optimise e-Label processes. Collaboration among regulatory bodies, healthcare professionals, patients, and industry groups is crucial for advancing e-Label in Asia. The Asia Partnership Conference of Pharmaceutical Associations (APAC), a coalition of thirteen pharmaceutical associations from eleven Asian markets, has advocated for faster access to innovative medicines since 2012.
In 2020, APAC began exploring e-Label, leading to the formation of an expert working group in 2021 to further this initiative.

	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				

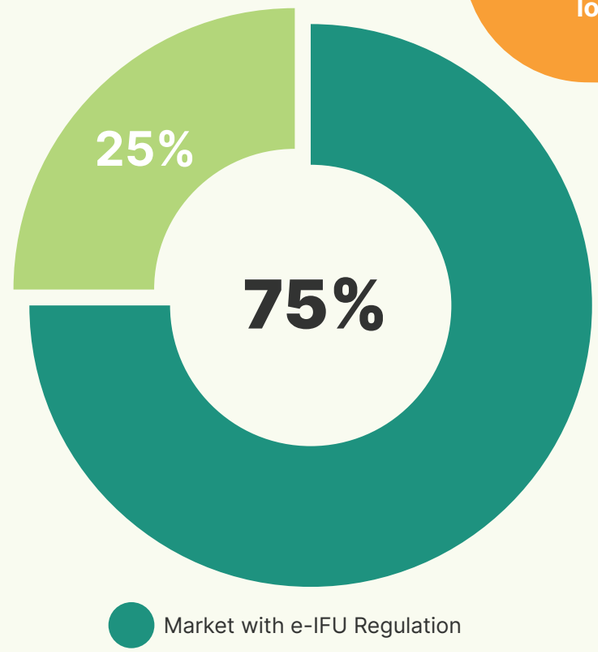
Table 2: Global e-Labelling Implementation Status in Pharma sector extracted from APAC e-Labelling EWG Position Paper 2023

Our survey revealed that, aside from Singapore and Malaysia, which have established some form of frameworks, there are currently no specific e-Label regulations for pharmaceutical products in other jurisdictions in the APAC region. This is in alignment with the findings from the aforementioned APAC survey.

Regulatory Landscape – Medical Device e-IFU

What does the medical device e-IFU Regulatory Landscape look like today?

...our survey of 45 respondents from the industry revealed that:



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.

Of the twelve APAC markets as consolidated in the e-IFU regulatory framework below, only three do not have specific e-IFU regulations at this stage. In most markets, e-IFU are permitted for professional use Medical Device, while four markets allow both professional use and home use Medical Device. e-IFU must be accessible either on the authority's website or the manufacturer's website. In all these markets, transitioning from paper IFU to e-IFU requires either a notification or approval from the health authority.

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	Manufacturer	Yes
China	No	NA	NA	NA
Chinese Taipei	Yes	Professional Use	Manufacturer	No
Japan	Yes	Professional Use	Health Authority	Yes
South Korea	Yes	Both**	Manufacturer	Yes
India	Yes	Both	Manufacturer	Yes
Indonesia	No	NA	NA	NA
Thailand	Yes	Both	Manufacturer	Yes
Philippines	No	NA	NA	NA
Vietnam	Yes	Both	Manufacturer	Yes
Singapore	Yes	Professional Use	Manufacturer	Yes
Malaysia	Yes	Professional Use	Manufacturer	Yes

Table 3: Summary of APAC Medical Device e-IFU Regulatory Landscape

* At the time of writing this paper (Jul 2024), 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.

Recommendations

Below are recommendations that APACMed offers on e-Label & e-IFU:

Consider Electronic Solutions for Product Label:
We encourage regulators to consider adopting electronic solutions for product labels to address the diverse and complex regional/country label requirements. Electronic product labels offer dynamic updates, ensuring real-time compliance with local regulations and allowing for easy customisation to meet specific needs. They enhance accessibility through multiple formats and multilingual support, making product information user-friendly and widely understandable. Additionally, electronic labels reduce printing costs, streamline processes, and support environmental sustainability by minimising paper use. Building on the success of e-IFUs, this approach promises a practical, efficient, and forward-thinking solution for the healthcare industry, ensuring safety, compliance, and adaptability.

01

Expand the Adoption of e-IFU to cover Home-Use/Consumer devices:
It is recommended that current medical device e-IFU regulations be expanded to include home-use/consumer devices. By explicitly stating this requirement in the regulation, regulators can ensure that manufacturers have clear expectations and compliance standards, thus avoiding ambiguity and providing a straightforward path for adherence. This clarity will ensure end-users receive updated, accurate and reliable information, capitalising on the benefits that electronic solutions have to offer. Additionally, updating the regulation to cover these increasingly prevalent devices will acknowledge and support this growing market segment, ensuring patients and caregivers have the necessary information to use these devices safely and effectively according to the device's intended use.

02

Harmonise, Standardise, and Ensure Interoperability Across Markets:
Harmonising e-IFU regulations across different markets would facilitate better adoption of e-IFUs, making the process more seamless and cost-effective. This simplifies compliance efforts and reduces the need for customisations for different regions, saving time and resources. Standardised regulations often result in higher safety and quality standards, as they are typically based on best practices and international standards. This helps ensure that medical devices meet consistent levels of safety and efficacy across different markets, benefiting both manufacturers and patients.

03

Conduct Thorough Risk Assessments:
Transitioning from paper-based IFU to electronic solutions necessitates a comprehensive risk assessment to ensure patient safety and enhance overall safety standards. The risk evaluation associated with paper-based IFUs will serve as the foundational assessment, building upon the conventional risks while incorporating additional considerations unique to digital platforms such as accessibility, user-friendliness, and reliability. e-IFU offers advantages, yet it also presents new challenges such as digital literacy & potential technological failures. Therefore, a thorough risk assessment helps identify and mitigate these risks, ensuring that the electronic solution does not compromise safety but rather, improves it compared to conventional paper-based methods. This diligent process ensures that the transition to e-IFUs not only maintains compliance with regulatory requirements but also prioritises patient safety and device efficacy. This is consistent with the MedTech Europe's calls[10] for the scope expansion of EU 2021/2226 on the use of e-IFUs, where a risk assessment to ensure users are using the device safely is critical and remains an obligation of the manufacturer.

04

Support Internet & Technology Penetration and Enhance User Digital Literacy:
To support the implementation of e-Label & e-IFU, it is crucial to address the challenges of internet & technology penetration and user digital literacy. A strategic approach involves accessing the digital landscape to identify areas with limited connectivity and providing a tailored digital literacy program to the impacted users. This ensures that all users, regardless of their location and digital proficiency, can access and utilise e-Label & e-IFU effectively. Such initiatives could include developing offline solutions like pre-loaded tablets or USB drives with instructions, conducting training sessions to enhance digital device usage skills, and partnering with telecommunication companies to improve network infrastructure. These steps are vital in ensuring that the transition to e-Label and e-IFU is inclusive and beneficial across diverse healthcare settings.

05

Maintain Printed Copies of IFU as Backup:
While e-IFU should be the primary method, manufacturers should also provide printed copies upon request. Users can also print out an IFU from the electronic source, which is an option for obtaining a paper IFU in a quick manner. This ensures that users who prefer or require paper instructions have access to them.

06

Conclusion

In conclusion, this position paper has delineated the advantages of implementing electronic solutions for product labels and IFU to augment healthcare efficiency. A comprehensive analysis of regional regulatory practices has been conducted, accompanied by actionable recommendations for stakeholders' reference. At APACMed, we will leverage this document as an instrumental resource to champion the integration of e-Label & e-IFU within the APAC region. This endeavour is in congruence with APACMed's mission of fostering regulatory harmonisation and convergence, which is pivotal in elevating patient care standards. We are also committed to promote capacity-building initiatives aimed at fortifying the competencies of the regulatory framework in this area.

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The voice of MedTech

About **APACMed**

The Asia Pacific Medical Technology Association (APACMed) represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations, and other key stakeholders associated with the medical technology industry in the Asia Pacific region. APACMed's mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia-Pacific. For more information, visit www.apacmed.org.

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