



**Asian Harmonization Working Party**  
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

**FINAL DOCUMENT**

**Title:** Regulation and treatment of e-IFU and e-Label of Medical Devices - Review of International Practice

**Authoring** Working Group 1 - Pre-market: General MD

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## **Executive Summary**

This White Paper presents a summary of current international practices for regulation of e-Labels and e-IFUs in a selection of representative jurisdictions including members of both IMDRF and AHWP.

The paper addresses the current and potential application of e-Labeling and e-IFUs in the healthcare industry and the attitudes and concerns surrounding it.

The information gathered and presented in this white paper shows that although there are areas of consensus and similarities of practice in the regulation of e-Labeling and e-IFUs, there are also areas of substantial difference between regulators. Key findings were:

- Most agencies do not accept electronic labels or IFUs.
- The majority of agencies regulate IFUs and Labels for medical devices.
- The greatest concern for most agencies was the accessibility issue for patients and health care professionals alike, particularly in rural regions.
- There is a similarity in application of manufacturing
- The definition of IFU and Label were almost identical across the agencies.
- Most agencies required approval for any update/changes to content for labels and IFU's.

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## 1 Introduction

e-Label and e-IFUs present unique challenges in management of the application of different regulatory requirements, review processes and the impact on patients. This review has been prepared by the e-Labeling working group of AHWP Study Group 1 to inform the AHWP Technical Committee as to the current regulatory practices for e-Labels and e-IFUs, and to provide a background to possible future guidance preparation by AHWP. The review has considered practices in both AHWP member jurisdictions, as well as in the members of the International Medical Device Regulatory Forum (IMDRF).

## 2 Definitions

### 2.1 e-Labeling

Labeling refers to information supplied by the manufacturer including label, IFUs, and additional information. E- Labeling refers to electronic versions of these documents, including e-Labels & e-IFUs.

### 2.2 e-Labels

According to the Global Harmonisation Task Force; Labels are written, graphic or printed communications usually attached to the medical device or its packaging. e-Label is the electronic version of labels, especially for Software as Medical Device (SaMD), when there is no physical media/product.

### 2.3 e-IFUs

Instructions for use or IFU refers to information provided by the manufacturer. It functions to notify the user on the device's intended purpose, precautions and other important information. e-IFU refers to the electronic version of this document.

## 3 Current Practice

Information on the current regulatory requirements and practices for the use of e-Labels and e-IFUs was collated using the framework of a standard questionnaire (**Appendix A**). This questionnaire was sent to regulatory agency representatives and/or industry members for completion and returned. Information was gathered for a range of AHWP and IMDRF members. For some of the more well-established agencies (including most IMDRF members), the information was gathered by a researcher based on available published materials including regulations, guidance documents and regulatory agency websites. The information compiled was then reviewed and is described and summarised below.

## 4 Regulatory Challenges for e-IFUs and e-Labels

The regulation of e-Labels and e-IFUs for medical devices presents a specific challenge in that the different advancements in technologies and current accepted practises globally. In particular, it is necessary to consider:

- Current regulations and guidelines;
- Practicality and impact of exclusively providing this information in a digital format;

- Environmental effects
- IT Infrastructures
- Compliance

All of these aspects can vary widely among regions and countries. The need to assess different IT infrastructures and different user technological attitudes will require a review processes to draw on expertise of multiple technical experts from different regulatory and Information technology divisions or agencies.

## **5 Current Practices**

The current practices for regulation of e-Label and e-IFUs are summarised in **Table 1**.

Detailed descriptions of requirements in individual jurisdictions are described in **Appendix B**.

The information gathered and presented in this white paper shows that although there are areas of consensus and similarities of practice in the regulation of e-Labels and e-IFUs. The following discussion summarises the areas of agreement and of difference attempts to identify the key technical and safety challenges arising from need to manage regulatory processes in tandem.

**Table 1 Summary of Regulation and potential barriers a of e-Labels and e-IFUs in International Jurisdictions**

	IFUs regulated	Content or update to IFU require approval?	IFU formats permitted	e-IFUs permitted & does this waive physical requirements	Labels regulated	Content or update to Labels require approval?	Label formats permitted	e-Labels permitted, does this waive physical requirements	Differences in regulatory control between IVD/MD	Potential barriers & Opportunities	Considerations in guidelines
<b>AHWP Members</b>											
<b>China</b>	Y	Y	C	N,A	Y	N	C	N,A	Y	H,O	K,N
<b>Hong Kong</b>	N	A	A	N,A	N	A	A	A	A	F,G,H,I,J	K,L
<b>India</b>	Y	Y	C	N,A	Y	Y	C	N,A	N	F,G,I	B
<b>Kazakhstan</b>	N	A	A	N,A	Y	Y	C	N,A	A	F	B
<b>Korea</b>	Y	N	C,D	N	Y	N	C	N	N	B	K,M
<b>Philippines</b>	Y	Y	C	N,A	Y	Y	C	N,A	N	F,G	N
<b>Saudi Arabia</b>	Y	Y	C	N,A	Y	B	C	N,A	B	F,O	L
<b>Singapore</b>	Y	Y	E	Y,N	Y	Y	C,D	Y,Y	Y	F	L,M
<b>Taiwan</b>	Y	Y,N	C	N,A	Y	Y,N	C	N,A	N	F,G,H	K,L,M
<b>Tanzania</b>	Y	Y	C	N,A	Y	Y	C	N,A	N	B	K
<b>Non-AHWP Members</b>											
<b>AUS<sup>1</sup></b>	Y	Y,N	E	N,A	Y	Y,N	E	N,A	Y	A	A
<b>CAN<sup>2</sup></b>	Y	Y,N	E	Y,N	Y	Y,N	E	Y,N	Y	A	A
<b>EC<sup>3</sup></b>	Y	Y,N	E	Y,N	Y	Y,N	E	Y,N	Y	A	A
<b>JPN<sup>4</sup></b>	N	A	A	A	Y	Y	E	Y	N	G	A
<b>USA<sup>5</sup></b>	Y	Y	E	Y,N	Y	Y,N	E	Y,N	Y	A	A

**Legend:**

Y: Yes

N: No

A: Not applicable

B: Not clear/Blank

C: Physical copy: Provided with the medical device

D: Digital Copy: provided with the medical device (CD, USB etc.)

E: Physical, Digital provided with the medical device and web-based/on screen not included with the Device. Restricted application, must comply with local requirements

F: Patients: Accessibility

G: Healthcare professionals: need paper, less incentive to read, accessibility

H: Regulations and/or local/international authorities

I: IT infrastructure: Accessibility, maintain updated versions

J: Supply chain: no effect on current stocks when IFU/Label updated

K: Introduce new or modify current regulations

L: Limit applicability e.g.: not to consumers

M: Develop the guidance for website validation and management

O: Other

<sup>1</sup> Sourced from Therapeutic Goods Administration website

<sup>2</sup> Sourced from Health Canada website

<sup>3</sup> Sourced from CE

<sup>4</sup> Specific Japan definition outlined with survey results

<sup>5</sup> Sourced from US Food and Drug Administration website

## 5.1 Regulation of Medical Device Label and IFU

Most agencies surveyed regulated labels and IFU's. This is not surprising –labels and IFUs for medical devices are vital in communicating to the user, be it healthcare professional or patients, important information about the device. The challenges for most is to establish new regulations and guidelines to firstly allow the use of e-Labels and e-IFUs and secondly the resources needed to both regulate and apply these changes.

The US, Europe, Canada, Japan and Singapore are the only jurisdictions surveyed which currently allow for electronic versions of IFU and Labels. Korea was under review to include electronic copies. Despite the permissions to allow e-Labels and e-IFUs, this was still heavily controlled. Factors such as the kind of devices, where the device is being used and the persons using the device determines whether e-Labels and e-IFUs are permitted. In all cases, e-Labels and e-IFUs were allowable for professional use only. Furthermore, a physical copy of IFU must be available to the user upon request.

## 5.2 Concerns and opportunities

The most prevalent concern among all jurisdictions surveyed is accessibility of e-IFUs and e-Labels. This is of particular concern for patients as users. It is pointed out that not all persons have access to computers or internet. An extension of this concern is IT infrastructure - not only internet availability, but also website accessibility. Are IFUs and labels able to be maintained to ensure current and relevant versions are reaching users.

Another barrier is that of healthcare professionals and medical institutions. In some facilities, it is a requirement for physical copies to be available. Another factor is whether it would be possible to ensure the healthcare professional or user would bother taking the extra step needed to access the documentation online. How would manufacturers ensure compliance is achieved?

Other barriers identified included regulations of local and global competent authorities. As seen in **Table 1**, most agencies do not allow for non-physical formats, they require review and approval of IFUs & labels. Changes to guidelines and regulations will need to be implemented and go through the appropriate country specific processes. Included in this process are the provisions of review of e-Labels, e-IFUs and their updates.

An opportunity identified is in terms of supply chain. With e-Labels and e-IFU's, there would be no impact on current stock levels when an updated IFU or label became active.

Environmental benefits were also recognised. e-Labels and e-IFUs provide an opportunity for decrease in paper waste, offering an environmentally friendly alternative.

## 5.3 Considerations to overcome barriers

A key step in consideration to overcome these barriers is the introduction or modification of current regulations and guidelines. This will be needed where agencies do not currently accept alternatives to physical copies. This is currently implemented in jurisdictions which allow e-Labels and e-IFUs to be used. Restrictions on the kind of device, who uses the devices and where the device will be used are all factors which needs to be considered.

In addition to this, development of guidance to ensure the websites where e-Labels and e-IFUs are being facilitated are validated and managed accordingly. This also provides an

added element of interdisciplinary action. An understanding of both regulatory requirements and IT platforms would be needed and security would need to be considered.

Limiting the applicability was another favourable consideration according to the surveyed jurisdictions. In particular the applicability to lay-persons or patients. Perhaps offering e-Labels and e-IFUS only to healthcare professionals is more feasible. It is more likely they would have access to obtain electronic copies. This has been considered for jurisdictions which currently allow for e-Label and e-IFU use. Most of them have restricted this access to professional use only and not for device sold to the general public.

## **6 Summary**

The regulation of e-Labels and e-IFUs is established in some jurisdictions. However, it's application is restricted. A similar adoption for the rest of the world seems inevitable, however, raises concerns and challenges. Apprehensions such as accessibility, applicability and IT infrastructure would need to be scrutinised by each jurisdiction independently, and regulations would need to reflect the specific jurisdiction's requirements. As such, a uniform approach may not be feasible in considering the implementation of e-Labels and e-IFUs for countries worldwide.



## Appendix A Questionnaire

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This Appendix provides a copy of the original questionnaire used for gathering the information used as input to this White Paper.

## Questionnaire on regulation and treatment of e-IFU and e-Label of Medical Devices by AHWP member economies

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In accordance to the advancement in technology and sophistication of users, electronic labelling (e-IFU & e-Label) have gained significant momentum and recognition. The traditional paper manuals are considered not ecological friendly, costly, and difficult to update. And the traditional paper label may not be practical for certain products, e.g. SaMD(Software as Medical Device) - Apps, etc.

Web-based e-IFU, web-based manual, or e-Label are alternate means to provide up-to-date information to users and patients without compromising patient's safety, and to improve user experience. Adoption of e-IFU or e-Label will also provide advantages to manufacturers. The e-IFU or e-Label allow manufacturers to provide more detailed information on Medical Device (such as Medical Device demo videos), improve safety, reduce costs, and simplify update process. In US and Europe, web-based e-IFU has been accepted as the replacement of physical IFU since 2004 and 2013, respectively.

- US FDA allows e-IFU for IVD for professional users, and prescription medical devices used by health care professionals, provided the website has been validated and documented, and company website address is included. Paper IFU can be provided per request by users.
- Europe Competent Authorities allows web-based e-IFU for IVD for professional users, implantable medical devices, and fixed installed medical devices in health care facilities. The website shall be in a commonly used format, be protected against hardware/software intrusion, be directly accessible and stable, and be searchable. The website shall also include Warning/Contraindication, and company website address. Paper IFU can be provided per request by users.

With rapid evolvement of technology and modernization, it is essential that enhanced labelling mechanisms being adopted as early as possible. In this regard, AHWP TC Working Group 1 and Working Group 2 are working towards development of guidance on electronic labelling.

AHWP TC Working Group 1 and Working Group 2 have prepared this questionnaire on e-IFU & e-Label to understand the current status and regulations, and to seek your feedback and comments on opportunities, challenges and potential barriers. Your valuable inputs will be used for the development of AHWP guidance for "e-IFU & e-Label as an alternate method for compliance to regulatory labelling requirements"

This questionnaire will be published either through online survey to enable easier retrieval and analysis, or in this word format to facilitate recording through interviews. Thank you for your cooperation in advance.

The questionnaire is divided into five sections.

1. Status on e-IFU
2. Status on e-Label
3. Opportunities and potential barriers
4. Suggestions
5. Demographic

## Section 1. Status on e-IFU

1. Is Medical Device IFU regulated in your country?
  - Yes
  - No (please direct to Question #2)
  
- 1.1. If yes for Question #1, please describe the definition of IFU and requirements on IFU including device scope and content under regulation.  
Click or tap here to enter text.
  
- 1.2. If yes for Question #1, does the content and the update of the content require approval by the Competent Authority before release?
  - Yes
  - No
  
- 1.3. If yes for Question #1, is there a difference of the regulatory control for IFU between medical devices and IVD medical devices?
  - Yes; the major differences are: Click or tap here to enter text.
  - No
  
- 1.4. If yes for Question #1, which of these IFU formats are allowed? (select all applied)
  - Physical IFU: Provided with the medical device
  - Physical IFU: Digital IFU provided with the medical device (CD, USB, DVD, etc.)
  - e-IFU: web-based e-IFU in electronic, not included with the medical device, but available to the customer at the time of use
  - e-IFU: On-screen e-IFU (connected to web, or embedded in software device)Other comments (if any): Click or tap here to enter text.
  
- 1.5. If yes for Question #1, does e-IFU waive regulatory requirements for physical IFU?
  - Yes
  - No (please direct to Question #2)
  
- 1.5.1. If yes for Question #1.5, please describe the local regulatory requirements on e-IFU including the medical device scope, e-IFU display requirements and format, traceability, website requirements and validity.  
Click or tap here to enter text.

1.5.2. If yes for Question #1.5, what is the level of usage of e-IFU vs. physical IFU?

- Majority use e-IFU
- Majority use physical IFU

1.5.3. If yes for Question #1.5, does your existing regulatory framework require application, reporting or assessment before use of change over from physical label to e-IFU?

- Yes; the procedure and requirement are basically as follow: Click or tap here to enter text.
- No

## Section 2. Status on e-Label

2. Is Medical Device Label regulated in your country?

- Yes
- No (please direct to Question #3)

2.1. If yes for Question #2, please describe the definition of Label and requirements on Label including device scope and content under regulation.

Click or tap here to enter text.

2.2. If yes for Question #2, does the content and the update of the content require approval by the Competent Authority before release?

- Yes
- No

2.3. If yes for Question #2, is there a difference of the regulatory control for Label between medical devices and IVD medical devices?

- Yes; the major differences are: Click or tap here to enter text.
- No

2.4. If yes for Question #2, which of these label formats are allowed? (select all applied)

- Physical label: Provided with the medical device
- Physical label: Digital label provided with the software medical device (label on jewel case of CD, USB, DVD, etc.)
- e-Label: web-based e-Label in electronic, not included with the medical device, but available to the customer at the time of use

- e-Label: On-screen e-Label embedded in software device (e.g. About Box, power-on screen)

Other comments (if any): [Click or tap here to enter text.](#)

2.5. If yes for Question #2, does e-Label waive regulatory requirements for physical label?

- Yes  
 No (please direct to Question #3)

2.5.1. If yes for Question #2.5, please describe the local regulatory requirements on e-Label including the medical device scope, e-Label display requirements and format, traceability, website requirements and validity.

[Click or tap here to enter text.](#)

2.5.2. If yes for Question #2.5, what is the level of usage of e-Label vs. physical label?

- Majority use e-Label  
 Majority use physical label

2.5.3. If yes for Question #2.5, does your existing regulatory framework require application, reporting or assessment before use of change over from physical label to e-Label?

- Yes; the procedure and requirement are basically as follow: [Click or tap here to enter text.](#)  
 No

### Section 3. Opportunities and potential barriers

3. Choose all potential barriers, challenges and opportunities are faced in adopting e-Label and/or e-IFU as an alternative method to traditional physical labelling (select all applied and specify concerns)

- Healthcare professionals (specify concerns: [Click or tap here to enter text.](#))  
 Patients (specify concerns: [Click or tap here to enter text.](#))  
 Local / International (Global) Competent Authorities (specify concerns: [Click or tap here to enter text.](#))  
 Regulations (specify concerns: [Click or tap here to enter text.](#))  
 IT infrastructures (specify concerns: [Click or tap here to enter text.](#))  
 Supply chain members - Manufacturers, Importers, and Distributors (specify concerns: [Click or tap here to enter text.](#))  
 Others (specify concerns: e.g. language translation, caution health/safety hazards, or indication of the nominal frequency, etc. [Click or tap here to enter text.](#))

#### Section 4. Suggestions

4. What should AHWP consider in the guidance for "e-IFU or e-Label as an alternate method for compliance to labelling requirement" to overcome potential barriers posed by different stakeholders: (select all applied and elaborate)
- Introduce New Regulations or modify the current regulation including estimated timeline of the regulation change (specify suggestions: [Click or tap here to enter text.](#))
  - Limit the applicability scope to selected MD/IVD types, e.g. for professional users, for lay persons (specify suggestions: [Click or tap here to enter text.](#))
  - Develop the guidance of website validation and management (specify suggestions: [Click or tap here to enter text.](#))
  - Any other areas of consideration (specify suggestions: [Click or tap here to enter text.](#))

#### Section 5. Demographic

5. Please describe the respondent.
- 5.1. Name:
- 5.2. Designation:
- 5.3. Organization:
- 5.4. Country:
- 5.5. Email address
- 5.6. Contact Number:
- 5.7. Select the type of work
- Regulator
  - Medical Device Industry (manufacturer, distributor, consultant)
  - Notified body
  - Testing lab
  - Healthcare professional
  - Others: [Click or tap here to enter text.](#)
- 5.8. Select all medical devices types you mostly face.
- Installed medical devices
  - Implantable medical devices
  - General use medical devices
  - IVD for self-testing by lay persons
  - IVD for professionals use
  - Others: [Click or tap here to enter text.](#)

6. Please describe the interviewer (if the interviewee did not enter responses in the form)
- 6.1. Name:
- 6.2. Designation:
- 6.3. Organization:
- 6.4. Country:
- 6.5. Email address:

Thank you so much for your participation. Your valuable answers will be a great asset in developing the AHWP guidance. Thank you.

## Appendix B Jurisdiction requirements

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In the alphabetical order.



# China

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## Section 1. Status on e-IFU

1. Is Medical Device IFU regulated in your country?

Yes

No (please direct to Question #2)

1.1. If yes for Question #1, please describe the definition of IFU and requirements on IFU including device scope and content under regulation.

### CFDA Order No. 6

**Article 3** Medical device IFU refers to the technical document produced by the medical device registration (filing) applicant, provided to users together with the product, and covering the basic information on the safety and efficacy of the product, and used for guiding the proper installation, calibration, operating, use, repair, and maintenance.

**Article 10** Medical device IFU generally should include the following contents:

- (I) Name, model and specification of product;
- (II) Name, address, contact information, and after-sales service unit of registration(filing) applicant; the name, address and contact of agent should also be indicated for imported medical devices;
- (III) Name, address, manufacture address, contact information and manufacture certificate number of manufacture and/or filing certificate number of manufacturer; the name, address, manufacture address, manufacture certificate number or manufacture filing certificate number of entrusted enterprise should also be indicated for contracted manufacture.
- (IV) Medical device registration certificate number or filing certificate number;
- (V) Number of technical requirement of product;
- (VI) Product performance, main structure and composition or ingredient, and scope of application;
- (VII) Contraindication, precaution, warning and prompting contents;
- (VIII) Instruction or graphic representation for installation and use; special instruction for safety use should be provided for the medical device used by individual consumer;
- (IX) Product repair and maintenance method, special storage and transportation conditions and methods;
- (X) Manufacture date, shelf-life or expiry date;
- (XI) List of parts, including explanation of the replacing cycle and replacement method of spare parts, accessories, and consumables;
- (XII) Interpretation of such contents as the graphics, symbols, abbreviations, etc. used by medical device label;
- (XIII) Compilation or revision date of IFU;
- (XIV) Other contents to be indicated.

**Article 11** The precautions, warnings, and promoting contents in medical device IFU mainly include:

- (I) Object of product use;
- (II) Potential safety hazard and service restrictions;
- (III) Protective measures for operator and user and emergency correction measures to be taken in case of accident occurred during the correct use of product;
- (IV) Necessary monitoring, evaluation, and control means;
- (V) Such words or symbols as “single-use” should be indicated for single-used products; the sterilization method and the treatment method after sterile packaging is damaged should be indicated for such sterilized product; and the disinfection or sterilization method should be specified for the product to be disinfected or sterilized before use;
- (VI) When the product is installed and used in combination with other medical devices, the requirements on the combined use of medical devices, application method, and precautions should be indicated;
- (VII) Mutual interference possibly occurred with other products and the potential hazard in the process of use;
- (VIII) Adverse event possibly caused in the use of product or component or auxiliary material contained in the component of product that may cause negative effect;
- (IX) Matters need attention for medical device wastes disposal; appropriate treatment method should be indicated for those products to be treated after use;
- (X) Other matters that should be reminded to operator and user according to the characteristics of product.

1.2. If yes for Question #1, does the content and the update of the content require approval by the Competent Authority before release?

- Yes
- No

1.3. If yes for Question #1, is there a difference of the regulatory control for IFU between medical devices and IVD medical devices?

- Yes; the major differences are: IFU changes will undergo change registration for IVDs, but for minor change for medical device IFU that have no impact to product safety and efficacy, IFU filing is sufficient.
- No

1.4. If yes for Question #1, which of these IFU formats are allowed? (select all applied)

- Physical IFU: Provided with the medical device
- Physical IFU: Digital IFU provided with the medical device (CD, USB, DVD, etc.)
- e-IFU: web-based e-IFU in electronic, not included with the medical device, but available to the customer at the time of use
- e-IFU: On-screen e-IFU (connected to web, or embedded in software device)

Other comments (if any):

1.5. If yes for Question #1, does e-IFU waive regulatory requirements for physical IFU?

Yes

No (please direct to Question #2)

## Section 2. Status on e-Label

2. Is Medical Device Label regulated in your country?

Yes

No (please direct to Question #3)

2.1. If yes for Question #2, please describe the definition of Label and requirements on Label including device scope and content under regulation.

### CFDA Order No. 6

**Article 3** Medical device label refers to the literal statement, graphics and symbols attached to medical device or its packaging used for identifying product characteristics and indicating safety and warning information, etc.

**Article 13** Medical device label generally should include the following contents:

- (I) Name, model and specification of product;
- (II) Name, address, and contact information of registration(filing)applicant; the name, address and contact information of agent should also be indicated for imported medical devices;
- (III) Medical device registration certificate number or filing certificate number;
- (IV) Name, address, manufacture address, contact information and manufacture certificate number of manufacture filing certificate number of manufacturer; the name, address, manufacture address, manufacture certificate number or manufacture filing certificate number of entrusted enterprise should also be indicated for contracted manufacture.
- (V) Manufacture date, shelf-life or expiry date;
- (VI) Connection conditions and input power of the power supply;
- (VII) Graphics, symbols and other relevant contents to be indicated according to characteristics of product;
- (VIII) Necessary warnings and precautions;
- (IX) Special storage and operating conditions or explanations;
- (X) The label of the medical device with destructive or negative affect on environment in use should include warning marks or Chinese warning indications;
- (XI) The label of radioactive or radiation medical device should include warning marks or Chinese warning indications. If above contents cannot be fully indicated due to the limitation of the position or size of medical device label, it should at least indicate the name, model, specification, manufacture date, service life or expiry date of product and clearly indicate that "for more detailed about other contents, see IFU" in the label.

- 2.2. If yes for Question #2, does the content and the update of the content require approval by the Competent Authority before release?
- Yes
- No
- 2.3. If yes for Question #2, is there a difference of the regulatory control for Label between medical devices and IVD medical devices?
- Yes; the major differences are:
- No
- 2.4. If yes for Question #2, which of these label formats are allowed? (select all applied)
- Physical label: Provided with the medical device
- Physical label: Digital label provided with the software medical device (label on jewel case of CD, USB, DVD, etc.)
- e-Label: web-based e-Label in electronic, not included with the medical device, but available to the customer at the time of use
- e-Label: On-screen e-Label embedded in software device (e.g. About Box, power-on screen)
- Other comments (if any):
- 2.5. If yes for Question #2, does e-Label waive regulatory requirements for physical label?
- Yes
- No (please direct to Question #3)

### Section 3. Opportunities and potential barriers

3. Choose all potential barriers, challenges and opportunities are faced in adopting e-Label and/or e-IFU as an alternative method to traditional physical labelling (select all applied and specify concerns)
- Healthcare professionals
- Patients
- Local / International (Global) Competent Authorities
- Regulations
- IT infrastructures
- Supply chain members - Manufacturers, Importers, and Distributors

Others

#### Section 4. Suggestions

4. What should AHWP consider in the guidance for "e-IFU or e-Label as an alternate method for compliance to labelling requirement" to overcome potential barriers posed by different stakeholders: (select all applied and elaborate)
- Introduce New Regulations or modify the current regulation including estimated timeline of the regulation change (specify suggestions: regulation does not rule out the use of e-version IFU and labelling, but in practice, it was interpreted that only paper based are acceptable. Shall raise this point in an educational context in addition to regulation clarification)
  - Limit the applicability scope to selected MD/IVD types, e.g. for professional users, for lay persons
  - Develop the guidance of website validation and management
  - Any other areas of consideration

# Hong Kong

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## Combination of three Survey Results

### Section 1. Status on e-IFU

1. Is Medical Device IFU regulated in your country?
- Yes
  - No (please direct to Question #2)

### Section 2. Status on e-Label

2. Is Medical Device Label regulated in your country?
- Yes
  - No (please direct to Question #3)

### Section 3. Opportunities and potential barriers

3. Choose all potential barriers, challenges and opportunities are faced in adopting e-Label and/or e-IFU as an alternative method to traditional physical labelling (select all applied and specify concerns)
- Healthcare professionals (specify concerns: [lower incentive to read the IFU](#))
  - Patients (specify concerns: [Inability to access internet, Accessibility of e-IFU and/or e-Label](#))
  - Local / International (Global) Competent Authorities (specify concerns: [how to review and approve of e-IFU and e-Label in a timely manner](#))
  - Regulations
  - IT infrastructures (specify concerns: [Maintain updated version and ensure the information could be accessible anytime](#))
  - Supply chain members - Manufacturers, Importers, and Distributors (specify concerns: [Better for e-IFU and/or e-Label version updates without impact current stocks](#))
  - Others

### Section 4. Suggestions

4. What should AHWP consider in the guidance for "e-IFU or e-Label as an alternate method for compliance to labelling requirement" to overcome potential barriers posed by different stakeholders: (select all applied and elaborate)

- Introduce New Regulations or modify the current regulation including estimated timeline of the regulation change (specify suggestions: [Start from lower risk class devices](#))
- Limit the applicability scope to selected MD/IVD types, e.g. for professional users, for lay persons (specify suggestions: [Limited to HCP](#))
- Develop the guidance of website validation and management
- Any other areas of consideration

# India

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## Section 1. Status on e-IFU

1. Is Medical Device IFU regulated in your country?

Yes

No (please direct to Question #2)

1.1. If yes for Question #1, please describe the definition of IFU and requirements on IFU including device scope and content under regulation.

In accordance with Rule 109 A of Drug and cosmetic act and rules 1945

1.2. If yes for Question #1, does the content and the update of the content require approval by the Competent Authority before release?

Yes

No

1.3. If yes for Question #1, is there a difference of the regulatory control for IFU between medical devices and IVD medical devices?

Yes

No

1.4. If yes for Question #1, which of these IFU formats are allowed? (select all applied)

Physical IFU: Provided with the medical device

Physical IFU: Digital IFU provided with the medical device (CD, USB, DVD, etc.)

e-IFU: web-based e-IFU in electronic, not included with the medical device, but available to the customer at the time of use

e-IFU: On-screen e-IFU (connected to web, or embedded in software device)

Other comments (if any):

1.5. If yes for Question #1, does e-IFU waive regulatory requirements for physical IFU?

Yes

No (please direct to Question #2)



## Section 2. Status on e-Label

2. Is Medical Device Label regulated in your country?

Yes

No (please direct to Question #3)

2.1. If yes for Question #2, please describe the definition of Label and requirements on Label including device scope and content under regulation.

In accordance with Rules 109 A of Drug and Cosmetic Act and Rules, 1945

2.2. If yes for Question #2, does the content and the update of the content require approval by the Competent Authority before release?

Yes

No

2.3. If yes for Question #2, is there a difference of the regulatory control for Label between medical devices and IVD medical devices?

Yes; the major differences are:

No

2.4. If yes for Question #2, which of these label formats are allowed? (select all applied)

Physical label: Provided with the medical device

Physical label: Digital label provided with the software medical device (label on jewel case of CD, USB, DVD, etc.)

e-Label: web-based e-Label in electronic, not included with the medical device, but available to the customer at the time of use

e-Label: On-screen e-Label embedded in software device (e.g. About Box, power-on screen)

Other comments (if any):

2.5. If yes for Question #2, does e-Label waive regulatory requirements for physical label?

Yes

No (please direct to Question #3)

### Section 3. Opportunities and potential barriers

3. Choose all potential barriers, challenges and opportunities are faced in adopting e-Label and/or e-IFU as an alternative method to traditional physical labelling (select all applied and specify concerns)
- Healthcare professionals
  - Patients (specify concerns: [Patients residing in rural area.](#))
  - Local / International (Global) Competent Authorities
  - Regulations
  - IT infrastructures (specify concerns: [In rural areas, Internet connectivity would be major concern.](#))
  - Supply chain members - Manufacturers, Importers, and Distributors
  - Others

### Section 4. Suggestions

4. What should AHWP consider in the guidance for "e-IFU or e-Label as an alternate method for compliance to labelling requirement" to overcome potential barriers posed by different stakeholders: (select all applied and elaborate)
- Introduce New Regulations or modify the current regulation including estimated timeline of the regulation change
  - Limit the applicability scope to selected MD/IVD types, e.g. for professional users, for lay persons
  - Develop the guidance of website validation and management
  - Any other areas of consideration (specify suggestions: [Suggestions can be discussed in AHWP meeting scheduled in December.](#))

# Japan

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**Comment: Japanese regulation legally requires medical devices a package insert containing essential information of medical device on a fixed format. In this questionnaire, we mean “label” is the insert and “IFU” is other documents which is not legally demanded such as a manual for patients or medical professionals.**

## Section 1. Status on e-IFU

1. Is Medical Device IFU regulated in your country?

Yes

No (please direct to Question #2)

## Section 2. Status on e-Label

2. Is Medical Device Label regulated in your country?

Yes

No (please direct to Question #3)

2.1. If yes for Question #2, please describe the definition of Label and requirements on Label including device scope and content under regulation.

Pharmaceuticals and Medical Devices Act (article 63-2) and the regulatory notifications demands to attach a package insert (containing essential instructions for use and safety / quality / administrative information, etc.) to medical devices.

2.2. If yes for Question #2, does the content and the update of the content require approval by the Competent Authority before release?

Yes Consultation with Pharmaceuticals and Medical Devices Agency (PMDA) is mandatory for all contents of Class IV devices and important safety information of Class I - III devices prior to their revision.

No

2.3. If yes for Question #2, is there a difference of the regulatory control for Label between medical devices and IVD medical devices?

Yes; the major differences are:

No

- 2.4. If yes for Question #2, which of these label formats are allowed? (select all applied)
- Physical label: Provided with the medical device
  - Physical label: Digital label provided with the software medical device (label on jewel case of CD, USB, DVD, etc.)
  - e-Label: web-based e-Label in electronic, not included with the medical device, but available to the customer at the time of use
  - e-Label: On-screen e-Label embedded in software device (e.g. About Box, power-on screen)

Other comments (if any): A manufacturer can omit the paper insert only if its electronic version is registered and provided on PMDA web-site and each medical institute agrees with omission.

- 2.5. If yes for Question #2, does e-Label waive regulatory requirements for physical label?
- Yes
  - No (please direct to Question #3)

- 2.5.1. If yes for Question #2.5, please describe the local regulatory requirements on e-Label including the medical device scope, e-Label display requirements and format, traceability, website requirements and validity.

A manufacturer can omit the paper insert only if its electronic version is registered and provided on PMDA web-site and each medical institute agrees with omission. Substitution for the paper insert is possible for any medical devices and their format and contents are identical.

- 2.5.2. If yes for Question #2.5, what is the level of usage of e-Label vs. physical label?
- Majority use e-Label
  - Majority use physical label

- 2.5.3. If yes for Question #2.5, does your existing regulatory framework require application, reporting or assessment before use of change over from physical label to e-Label?
- Yes; the procedure and requirement are basically as follow:
  - No

### Section 3. Opportunities and potential barriers

3. Choose all potential barriers, challenges and opportunities are faced in adopting e-Label and/or e-IFU as an alternative method to traditional physical labelling (select all applied and specify concerns)
- Healthcare professionals (specify concerns: [they have a need for the paper insert. If a medical institution agrees, its omission is possible.](#))
  - Patients
  - Local / International (Global) Competent Authorities
  - Regulations
  - IT infrastructures
  - Supply chain members - Manufacturers, Importers, and Distributors
  - Others

### Section 4. Suggestions

4. What should AHWP consider in the guidance for "e-IFU or e-Label as an alternate method for compliance to labelling requirement" to overcome potential barriers posed by different stakeholders: (select all applied and elaborate)
- Introduce New Regulations or modify the current regulation including estimated timeline of the regulation change
  - Limit the applicability scope to selected MD/IVD types, e.g. for professional users, for lay persons
  - Develop the guidance of website validation and management
  - Any other areas of consideration
- [\\* Japan had already introduced a regulatory scheme for substituting a paper insert with its electronic document.](#)

# Kazakhstan

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## Section 1. Status on e-IFU

1. Is Medical Device IFU regulated in your country?

- Yes
- No (please direct to Question #2)

## Section 2. Status on e-Label

2. Is Medical Device Label regulated in your country?

- Yes
- No (please direct to Question #3)

2.1. If yes for Question #2, please describe the definition of Label and requirements on Label including device scope and content under regulation.

The label for medical device is being provided within registration dossier during MD registration, in case of positive and MD being registered, its label is uploaded to the national medicine and medical device registry. The label of every incoming batch of registered MD is compared to that in registry.

2.2. If yes for Question #2, does the content and the update of the content require approval by the Competent Authority before release?

- Yes
- No

2.3. If yes for Question #2, is there a difference of the regulatory control for Label between medical devices and IVD medical devices?

- Yes; the major differences are:
- No

2.4. If yes for Question #2, which of these label formats are allowed? (select all applied)

- Physical label: Provided with the medical device
- Physical label: Digital label provided with the software medical device (label on jewel case of CD, USB, DVD, etc.)
- e-Label: web-based e-Label in electronic, not included with the medical device, but available to the customer at the time of use

- e-Label: On-screen e-Label embedded in software device (e.g. About Box, power-on screen)

Other comments (if any):

2.5. If yes for Question #2, does e-Label waive regulatory requirements for physical label?

- Yes
- No (please direct to Question #3)

### Section 3. Opportunities and potential barriers

3. Choose all potential barriers, challenges and opportunities are faced in adopting e-Label and/or e-IFU as an alternative method to traditional physical labelling (select all applied and specify concerns)

- Healthcare professionals
- Patients (specify concerns: [The e-Labeling could be not available in certain cases and to certain consumers](#))
- Local / International (Global) Competent Authorities
- Regulations
- IT infrastructures
- Supply chain members - Manufacturers, Importers, and Distributors
- Others

### Section 4. Suggestions

4. What should AHWP consider in the guidance for "e-IFU or e-Label as an alternate method for compliance to labelling requirement" to overcome potential barriers posed by different stakeholders: (select all applied and elaborate)

- Introduce New Regulations or modify the current regulation including estimated timeline of the regulation change
- Limit the applicability scope to selected MD/IVD types, e.g. for professional users, for lay persons
- Develop the guidance of website validation and management
- Any other areas of consideration

# Korea

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## Section 1. Status on e-IFU

1. Is Medical Device IFU regulated in your country?

Yes

No (please direct to Question #2)

1.1. If yes for Question #1, please describe the definition of IFU and requirements on IFU including device scope and content under regulation.

“IFU” is a handbook or a manual that provides additional information about the product needed to be appropriately used.

Korean Regulations on IFU are provided as below.

### **Article 22 (Labeling on Package Inserts) of Medical Device Act**

(1) A package insert of a medical device shall include the following:

1. The method of, and precautions for, use;
2. Instructions for maintenance and inspections, if maintenance and inspections are required;
3. Matters that the Minister of Food and Drug Safety requires to be described pursuant to Article 19;
4. Other matters prescribed by Ordinance of the Prime Minister.

(2) The package inserts under paragraph (1) may be furnished in the form of a diskette, a CD-ROM or other electronic media, or a printed manual.

### **Article 43 (Description on Attached documents) of Enforcement Regulations of Medical Device Act**

① The “information determined by the Ministerial Decree of the Ministry of Food and Drug Safety” as provided in Item 4 of Article 22 of the Act shall mean the following items:

1. Matters of Items 1 to 3 and Items 5 to 7 of Article 20 of the Act;
2. Intended use of the product;
3. Keeping or storage method;
4. If the product is entrustment of all manufacturing processes, name and address of the manufacturer or the importer (the person who entrusted the shall be indicated as a “person who requested manufacturing”, the entrusted person, as “Manufacturer”, and in case of , country and company name);



5. If packing is available in each one in a bundle, the model and manufacturer name, which shall be described in the smallest packing unit;
6. In case of medical devices reusable after sterilization, information concerning proper procedure for reuse including the cleaning, sterilization, packing, re-sterilization method, and the limit on the number of times of reuse;
7. In case of medical devices emitting radiation for medical treatment, matters concerning characteristics, types, strength, and diffusion of radiation; and
8. Year and Month of preparation of attached documents
9. Other technical information such as the characteristics of the medical device.

② Notwithstanding Paragraph 1, information to be included in the attached documents of medical devices for clinical trial shall be as follows:

1. Indication of "For a clinical trial";
2. Product name and model name;
3. Manufacture number and date of manufacture (if the expiration date is specified, it may be described);
4. Keeping (storage) method;
5. Company name of the manufacturer or the importer (including the manufacturer or the country in case of entrusted manufacture or import, respectively); and
6. Indication of "Prohibition of use for any purposes other than clinical trial"

③ If the information on Items 1 through 7 of Paragraph 1 are described on the container or wrapper, or packing, such information may be omitted in the attached documents.

1.2. If yes for Question #1, does the content and the update of the content require approval by the Competent Authority before release?

Yes

No

1.3. If yes for Question #1, is there a difference of the regulatory control for IFU between medical devices and IVD medical devices?

Yes; the major differences are:

No

1.4. If yes for Question #1, which of these IFU formats are allowed? (select all applied)

Physical IFU: Provided with the medical device

Physical IFU: Digital IFU provided with the medical device (CD, USB, DVD, etc.)

- e-IFU: web-based e-IFU in electronic, not included with the medical device, but available to the customer at the time of use
- e-IFU: On-screen e-IFU (connected to web, or embedded in software device)

1.5. If yes for Question #1, does e-IFU waive regulatory requirements for physical IFU?

- Yes
- No (please direct to Question #2)

## Section 2. Status on e-Label

2. Is Medical Device Label regulated in your country?

- Yes
- No (please direct to Question #3)

2.1. If yes for Question #2, please describe the definition of Label and requirements on Label including device scope and content under regulation.

“Label” is written or printed information about the product that is either attached or printed directly on a container or article.

Korean Regulations on labeling are provided as below.

### Article 20 (Labeling on Containers, etc.) of Medical Device Act

The following descriptions shall be labeled on a container or an outer package of a medical device: Provided, That the foregoing shall not apply to a container or an outer package prescribed by Ordinance of the Prime Minister:

1. The trade name and address of the manufacturer or importer;
2. If imported, the origin of manufacture (the name of the country of manufacture and of the manufacturer);
3. The name of item, the name of model, and the approval (certification or notification) number;
4. The manufacturing number and the date of manufacturing (the use-by date may be stated in lieu of the date of manufacturing, if the use-by date exists);
5. Weight or packaging unit;
6. A label stating "medical device";
7. A "single-use only" and "do not reuse" label for a single-use medical device.

2.2. If yes for Question #2, does the content and the update of the content require approval by the Competent Authority before release?

Yes

No

2.3. If yes for Question #2, is there a difference of the regulatory control for Label between medical devices and IVD medical devices?

Yes; the major differences are:

No

2.4. If yes for Question #2, which of these label formats are allowed? (select all applied)

Physical label: Provided with the medical device

Physical label: Digital label provided with the software medical device (label on jewel case of CD, USB, DVD, etc.)

e-Label: web-based e-Label in electronic, not included with the medical device, but available to the customer at the time of use

e-Label: On-screen e-Label embedded in software device (e.g. About Box, power-on screen)

Other comments (if any):

2.5. If yes for Question #2, does e-Label waive regulatory requirements for physical label?

Yes

No (please direct to Question #3)

### Section 3. Opportunities and potential barriers

3. Choose all potential barriers, challenges and opportunities are faced in adopting e-Label and/or e-IFU as an alternative method to traditional physical labelling (select all applied and specify concerns)

Healthcare professionals

Patients

Local / International (Global) Competent Authorities

Regulations

IT infrastructures

Supply chain members - Manufacturers, Importers, and Distributors

Others

### Section 4. Suggestions

4. What should AHWP consider in the guidance for "e-IFU or e-Label as an alternate method for compliance to labelling requirement" to overcome potential barriers posed by different stakeholders: (select all applied and elaborate)

Introduce New Regulations or modify the current regulation including estimated timeline of the regulation change (specify suggestions: Korea MFDS is currently modifying the current regulation to implement e-labeling and e-IFU appropriately.)

(Contents of Revision)

① Indication that attached documents are provided online on Internet Homepage and Internet Homepage address (In case of providing attached document on Internet Homepage according to items 2 and 3 of article 22 of Medical Device Act)

② Internet Homepage (medical devices that are designated by the Minister of Ministry of Food and Drug Safety and utilized only in medical facility based on article 3 of medical law)

(Supplementary regulations) This act will be effective 6 months after the declaration

\* It is revised as legislation by Assembly members and the passing of this bill is undecided.

Limit the applicability scope to selected MD/IVD types, e.g. for professional users, for lay persons

Develop the guidance of website validation and management (specify suggestions: If needed, Korea MFDS will develop relevant guidelines, but we currently do not have guidance of website validation and management.)

Any other areas of consideration

# Philippines

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## Section 1. Status on e-IFU

1. Is Medical Device IFU regulated in your country?

Yes

No (please direct to Question #2)

1.1. If yes for Question #1, please describe the definition of IFU and requirements on IFU including device scope and content under regulation.

IFUs are included in the technical file to be submitted during the registration of the products. This include the intended use of the product, direction for use, indication/contraindication, warnings, precautions, special instruction and the like. Any change in the IFU once the product is registered, the company should apply for amendment or variation of the issued certificate of product registration (CPR)

1.2. If yes for Question #1, does the content and the update of the content require approval by the Competent Authority before release?

Yes

No

1.3. If yes for Question #1, is there a difference of the regulatory control for IFU between medical devices and IVD medical devices?

Yes; the major differences are:

No

1.4. If yes for Question #1, which of these IFU formats are allowed? (select all applied)

Physical IFU: Provided with the medical device

Physical IFU: Digital IFU provided with the medical device (CD, USB, DVD, etc.)

e-IFU: web-based e-IFU in electronic, not included with the medical device, but available to the customer at the time of use

e-IFU: On-screen e-IFU (connected to web, or embedded in software device)

Other comments (if any):

1.5. If yes for Question #1, does e-IFU waive regulatory requirements for physical IFU?

Yes

No (please direct to Question #2)

## Section 2. Status on e-Label

2. Is Medical Device Label regulated in your country?

Yes

No (please direct to Question #3)

2.1. If yes for Question #2, please describe the definition of Label and requirements on Label including device scope and content under regulation.

Labels are information attached to the product, the package. This also includes product insert, brochure as the case maybe. These are also part of the technical documentation needed during the product registration. Included in the label are the international labelling aside from our local labelling requirement which includes the placing of the name and address of the importer/distributor and the product registration number. Any changes in the label will require the filing of amendment/variation application for the CPR.

2.2. If yes for Question #2, does the content and the update of the content require approval by the Competent Authority before release?

Yes

No

2.3. If yes for Question #2, is there a difference of the regulatory control for Label between medical devices and IVD medical devices?

Yes

No

2.4. If yes for Question #2, which of these label formats are allowed? (select all applied)

Physical label: Provided with the medical device

Physical label: Digital label provided with the software medical device (label on jewel case of CD, USB, DVD, etc.)

e-Label: web-based e-Label in electronic, not included with the medical device, but available to the customer at the time of use

e-Label: On-screen e-Label embedded in software device (e.g. About Box, power-on screen)

Other comments (if any):

2.5. If yes for Question #2, does e-Label waive regulatory requirements for physical label?

Yes

No (please direct to Question #3)

### Section 3. Opportunities and potential barriers

3. Choose all potential barriers, challenges and opportunities are faced in adopting e-Label and/or e-IFU as an alternative method to traditional physical labelling (select all applied and specify concerns)
- Healthcare professionals
  - Patients
  - Local / International (Global) Competent Authorities
  - Regulations
  - IT infrastructures
  - Supply chain members - Manufacturers, Importers, and Distributors
  - Others (specify concerns: *not all parts of the country have access to computers/wifi where individuals or even a healthcare facilities can access the e-Label at any time. This will affect the health care delivery system in the country.* )

### Section 4. Suggestions

4. What should AHWP consider in the guidance for "e-IFU or e-Label as an alternate method for compliance to labelling requirement" to overcome potential barriers posed by different stakeholders: (select all applied and elaborate)
- Introduce New Regulations or modify the current regulation including estimated timeline of the regulation change
  - Limit the applicability scope to selected MD/IVD types, e.g. for professional users, for lay persons
  - Develop the guidance of website validation and management
  - Any other areas of consideration (specify suggestions: *I do not recommend pushing through the e-IFU or e-Label. Printed label is still the best way to ensure safety of use any part of the country.*)

# Saudi Arabia

## Status on Label and IFU requirements in general

Submitting Labelling to SFDA	1.	<p>Labelling provided to SFDA shall be complied with:</p> <ul style="list-style-type: none"> <li>▪ the relevant regulatory requirements applicable in one or more of the jurisdictions of Australia, Canada, Japan, the USA and the EU/EFTA (SFDA requires copies of all labelling as they were submitted and approved by the relevant regulatory authority), and</li> <li>▪ the provisions specific to the KSA concerning labelling and conditions of supply and/or use.</li> </ul> <p>Applicants providing information for MDMA purposes shall submit copies of all labelling, in the format that will be used when the device is marketed within the KSA, to the SFDA website. The SFDA will confirm, in particular, they satisfy requirements in respect of product identification, language, and tracking of individual devices through the supply chain.</p>
	2.	<p>Where labelling is provided in Arabic and/or English, it shall be submitted by the manufacturer.</p>
Language of Labelling	3.	<p>Where the user of the medical device is:</p> <ul style="list-style-type: none"> <li>▪ likely to be professionally qualified, labelling shall be in English</li> <li>▪ a lay person, the LABEL and IFU shall be, wherever feasible, in both Arabic and English (including that on any display). Where this is not feasible, the language used on the LABEL and IFU shall be Arabic.</li> </ul> <p>In both situations, the text shall be written in terms readily understood by the intended user, commensurate with their technical knowledge, experience, education or training.</p>
Language of Manufacturer's Instructions	4.	<p>Instructions for the handling, storage, transportation, installation, maintenance and disposal of the medical devices shall be in English and, where justified, in Arabic. The text shall be written in terms readily understood by the intended user, commensurate with their technical knowledge, experience, education or training where such work may be undertaken by persons without medical qualification.</p> <p>Where the device is intended to be used by lay persons, instructions for the handling, storage, transportation, maintenance of the medical devices shall be in both Arabic and English. The text shall be written in terms readily understood by the intended user, commensurate with their technical knowledge, experience, education or training where such work may be undertaken by persons without medical qualification.</p>
Power Supply	5.	<p>Where the device is intended to be connected to an a/c power supply, the label and the IFU shall indicate the nominal frequency (60 Hertz) and the voltage values with their tolerances for which the devices have been designed. (For information on the national requirement on nominal</p>



		voltage, see the council of ministers resolution number 324 dated on 20/9/1431 H for the approval of changing the voltage of electricity distribution for residential and commercial establishments in the new areas and for new subscribers in the existing areas from (127/220) volts to the voltage (230/400) volt).
Environmental Factors	6.	The IFU shall provide information on any measures taken to accommodate the specific non-electrical environmental and/or conditions of use encountered in the KSA, such as (a) local operating temperature and humidity conditions and (b) the level of protection of the devices against electro-magnetic disturbances, when applicable.
Medium of Labelling	7.	Labels shall be provided in a human-readable format but may be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.
	8.	<p>Where IFU are provided to the user in a non-paper format, such as downloaded from the manufacturer’s website using the internet, the means chosen must be appropriate for, and accessible to, the anticipated user population. Also, the manufacturer shall ensure the user has information on how to:</p> <ul style="list-style-type: none"> <li>▪ view the IFU.</li> <li>▪ identify and access the correct version of the IFU use.</li> <li>▪ obtain a paper version of the IFU.</li> </ul> <p>Where the device is intended for use by lay persons, the IFU shall be provided in a paper format.</p>
Advertising	9.	Advertising and marketing information shall be in English, or where the device is intended to be used by lay persons, in Arabic.
Logo of SFDA or Another Jurisdiction	10.	Labelling shall not include the SFDA logo nor the Establishment National Registry Number, that is issued by the SFDA through SFDA’s MDNR, but may include the Medical Device National Listing Number issued by the SFDA through SFDA’s MDMA.
	11.	The SFDA has the right to request evidence when labelling includes a symbol/logo (e.g. CE Marking) used by another jurisdiction to indicate the device complies with the relevant regulations of that other jurisdiction.
Note	12.	Please note that, the labelling requirements of Saudi customs may differ from SFDA requirements of marketing authorisation. Information on customs requirements is available on <a href="#">Saudi customs’ website</a> . However, SFDA staff will ensure that the manufacturing site of the country of origin, shown on the labelling of the imported devices, is covered by the documents provided to SFDA through MDMA submission.

### Section 1. Status on e-Label

1. Is Medical Device Label regulated in your country?
- Yes
- No (please direct to Question #2)
- 1.1. If yes for Question #1, which of these label formats are allowed? (select all applied)
- Physical label: Attachment with the device
- Physical label: label provided with the software device (label on jewel case of CD, USB, DVD, etc.)
- e-Label: web-based e-Label in electronic or printed form, not included with the device, but available to the customer at the time of use
- e-Label: On-screen e-Label embedded in software device (e.g. About Box, power-on screen)
- Other comments (if any):
- 1.2. If yes for Question #1, does e-Label waive regulatory requirement for physical label?
- Yes
- No (please direct to Question #2)

### Section 2. Status on e-IFU

2. Is Medical Device IFU regulated in your country?
- Yes
- No (please direct to Question #3)
- 2.1. If yes for Question #2, which of these IFU formats are allowed? (select all applied)
- Physical IFU: Attachment with the device
- Physical IFU: Digital IFU provided with the device (CD, USB, DVD, etc.)
- e-IFU: web-based e-IFU in electronic or printed form, not included with the device, but available to the customer at the time of use
- e-IFU: On-screen e-IFU (connected to web, or embedded in software device)
- Other comments (if any):
- 2.2. If yes for Question #2, does e-IFU waive regulatory requirement for physical IFU?
- Yes
- No (please direct to Question #3)

### Section 3. Potential barriers

3. Which potential barriers and challenges are faced in adopting e-Label and/or e-IFU as an alternative method to traditional physical labelling (select all applied and specify concerns)
- Users and Patients
  - Regulators
  - Regulations
  - IT infrastructures
  - Industry
  - Others (specify concerns: Translation to country's language; Indication of the nominal frequency on the label and the IFU i.e.(50/60 Hertz) / (110-220 Volt); Caution Health/Safety Hazards.)

### Section 4. Suggestions

4. What should AHWP consider in the guidance for "e-Label or e-IFU as an alternate method for compliance to labelling requirement" to overcome potential barriers posed by different stakeholders: (select all applied and elaborate)
- Enact New Regulations or modify the current regulation including estimated timeline of the regulation change
  - Limit the applicability scope to selected MD types, e.g. professional users, not consumer
  - Guidance of website validation and management
  - Any other areas of consideration

# Singapore

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## Section 1. Status on e-IFU

1. Is Medical Device IFU regulated in your country?

Yes

No (please direct to Question #2)

1.1. If yes for Question #1, please describe the definition of IFU and requirements on IFU including device scope and content under regulation.

**Definition:** INSTRUCTIONS FOR USE: Information provided by the product owner to inform the device user of the product's proper use and of any precautions to be taken.

**Requirements:** Please refer to *GN-23: Guidance on Labelling for Medical Devices (Draft)* which can be found at

[http://www.hsa.gov.sg/content/hsa/en/Health\\_Products\\_Regulation/Medical\\_Devices/Overview/Guidances\\_for\\_Medical\\_Device\\_Registration.html#draft\\_guidance](http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Overview/Guidances_for_Medical_Device_Registration.html#draft_guidance). Note that the guidance is currently in draft stage and is pending revision prior to release.

1.2. If yes for Question #1, does the content and the update of the content require approval by the Competent Authority before release?

Yes

No

1.3. If yes for Question #1, is there a difference of the regulatory control for IFU between medical devices and IVD medical devices?

Yes; the major differences are: Please refer to *GN-23: Guidance on Labelling for Medical Devices (Draft)* which can be found at

[http://www.hsa.gov.sg/content/hsa/en/Health\\_Products\\_Regulation/Medical\\_Devices/Overview/Guidances\\_for\\_Medical\\_Device\\_Registration.html#draft\\_guidance](http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Overview/Guidances_for_Medical_Device_Registration.html#draft_guidance).

No

1.4. If yes for Question #1, which of these IFU formats are allowed? (select all applied)

Physical IFU: Provided with the medical device

Physical IFU: Digital IFU provided with the medical device (CD, USB, DVD, etc.)

e-IFU: web-based e-IFU in electronic, not included with the medical device, but available to the customer at the time of use

e-IFU: On-screen e-IFU (connected to web, or embedded in software device)

Other comments (if any): e-IFU is restricted to the following: (i) MDs that are for use by healthcare professional only (ii) contact lenses and (iii) standalone software

1.5. If yes for Question #1, does e-IFU waive regulatory requirements for physical IFU?

Yes

No (please direct to Question #2)

1.5.1. If yes for Question #1.5, please describe the local regulatory requirements on e-IFU including the medical device scope, e-IFU display requirements and format, traceability, website requirements and validity.

Regulatory requirements on the contents are the same for both physical IFU and e-IFU. For e-IFU, there is an additional requirement to ensure that the internet or weblink, which allow users access to e-IFU must be clearly printed on the physical label of the device and displayed in such a manner that alerts the user to its purpose.

1.5.2. If yes for Question #1.5, what is the level of usage of e-IFU vs. physical IFU?

Majority use e-IFU

Majority use physical IFU

1.5.3. If yes for Question #1.5, does your existing regulatory framework require application, reporting or assessment before use of change over from physical label to e-IFU?

Yes

No

## Section 2. Status on e-Label

2. Is Medical Device Label regulated in your country?

Yes

No (please direct to Question #3)

2.1. If yes for Question #2, please describe the definition of Label and requirements on Label including device scope and content under regulation.

**Definition:** "label", in relation to a health product or an active ingredient, means any written, printed or graphic representation that appears on or is attached to the health product or active ingredient or any part of its packaging, and includes any informational sheet or leaflet that accompanies the health product or active ingredient when it is being supplied

**Requirements:** Please refer to *GN-23: Guidance on Labelling for Medical Devices (Draft)* which can be found at

[http://www.hsa.gov.sg/content/hsa/en/Health\\_Products\\_Regulation/Medical\\_Devices/Overview/Guidances\\_for\\_Medical\\_Device\\_Registration.html#draft\\_guidance](http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Overview/Guidances_for_Medical_Device_Registration.html#draft_guidance). Note that the guidance is currently in draft stage and is pending revision prior to release.

2.2. If yes for Question #2, does the content and the update of the content require approval by the Competent Authority before release?

Yes

No

2.3. If yes for Question #2, is there a difference of the regulatory control for Label between medical devices and IVD medical devices?

Yes; the major differences are: If the device is an in vitro diagnostic medical device, it must be labelled as “in vitro diagnostic” or “IVD”.

No

2.4. If yes for Question #2, which of these label formats are allowed? (select all applied)

Physical label: Provided with the medical device

Physical label: Digital label provided with the software medical device (label on jewel case of CD, USB, DVD, etc.)

e-Label: web-based e-Label in electronic, not included with the medical device, but available to the customer at the time of use

e-Label: On-screen e-Label embedded in software device (e.g. About Box, power-on screen)

Other comments (if any): e-Label may be considered for standalone software.

2.5. If yes for Question #2, does e-Label waive regulatory requirements for physical label?

Yes

No (please direct to Question #3)

2.5.1. If yes for Question #2.5, please describe the local regulatory requirements on e-Label including the medical device scope, e-Label display requirements and format, traceability, website requirements and validity.

e-Label may be considered for MD standalone software.

2.5.2. If yes for Question #2.5, what is the level of usage of e-Label vs. physical label?

- Majority use e-Label
- Majority use physical label

2.5.3. If yes for Question #2.5, does your existing regulatory framework require application, reporting or assessment before use of change over from physical label to e-Label?

- Yes
- No

### Section 3. Opportunities and potential barriers

3. Choose all potential barriers, challenges and opportunities are faced in adopting e-Label and/or e-IFU as an alternative method to traditional physical labelling (select all applied and specify concerns)

- Healthcare professionals
- Patients (specify concerns: [Inaccessibility of e-IFU](#))
- Local / International (Global) Competent Authorities
- Regulations
- IT infrastructures
- Supply chain members - Manufacturers, Importers, and Distributors
- Others

### Section 4. Suggestions

4. What should AHWP consider in the guidance for "e-IFU or e-Label as an alternate method for compliance to labelling requirement" to overcome potential barriers posed by different stakeholders: (select all applied and elaborate)

- Introduce New Regulations or modify the current regulation including estimated timeline of the regulation change
- Limit the applicability scope to selected MD/IVD types, e.g. for professional users, for lay persons
- Develop the guidance of website validation and management
- Any other areas of consideration

# Taiwan

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## Section 1. Status on e-IFU

1. Is Medical Device IFU regulated in your country?

Yes

No (please direct to Question #2)

1.1. If yes for Question #1, please describe the definition of IFU and requirements on IFU including device scope and content under regulation.

The Article 75 of Taiwan's Pharmaceutical Affairs Act specifies that the labels, instructions for use and packages of medical devices (including IVD) shall indicate the following particulars as approved:

1. Name and address of the manufacturer;
2. Name of the medicament and permit license number;
3. Lot number;
4. Date of manufacture and period of validity or shelf-life;
5. Major ingredients, dosage and method of administration;
6. Major medical efficacy, functions, and indications;
7. Side effect, counter-indications and other warnings; and
8. Other particulars as required by relevant regulations.

1.2. If yes for Question #1, does the content and the update of the content require approval by the Competent Authority before release?

Yes, for the parts of class II and class III medical devices (including IVD).

No, for the part of class I medical devices (including IVD).

1.3. If yes for Question #1, is there a difference of the regulatory control for IFU between medical devices and IVD medical devices?

Yes

No

1.4. If yes for Question #1, which of these IFU formats are allowed? (select all applied)

Physical IFU: Provided with the medical device

Physical IFU: Digital IFU provided with the medical device (CD, USB, DVD, etc.)

e-IFU: web-based e-IFU in electronic, not included with the medical device, but available to the customer at the time of use

e-IFU: On-screen e-IFU (connected to web, or embedded in software device)



Other comments (if any):

1.5. If yes for Question #1, does e-IFU waive regulatory requirements for physical IFU?

Yes

No (please direct to Question #2)

## Section 2. Status on e-Label

2. Is Medical Device Label regulated in your country?

Yes

No (please direct to Question #3)

2.1. If yes for Question #2, please describe the definition of Label and requirements on Label including device scope and content under regulation.

The Article 75 of Taiwan's Pharmaceutical Affairs Act (PAA) specifies that the labels, Instructions for Use and packages of medical devices (including IVD) shall indicate the following particulars as approved:

1. Name and address of the manufacturer;
2. Name of the medicament and permit license number;
3. Lot number;
4. Date of manufacture and period of validity or shelf-life;
5. Major ingredients, dosage and method of administration;
6. Major medical efficacy, functions, and indications;
7. Side effect, counter-indications and other warnings; and
8. Other particulars as required by relevant regulations.

2.2. If yes for Question #2, does the content and the update of the content require approval by the Competent Authority before release?

Yes, for the parts of class II and class III medical devices (including IVD).

No, for the part of class I medical devices (including IVD).

2.3. If yes for Question #2, is there a difference of the regulatory control for Label between medical devices and IVD medical devices?

Yes; the major differences are:

No

2.4. If yes for Question #2, which of these label formats are allowed? (select all applied)

- Physical label: Provided with the medical device
- Physical label: Digital label provided with the software medical device (label on jewel case of CD, USB, DVD, etc.)
- e-Label: web-based e-Label in electronic, not included with the medical device, but available to the customer at the time of use
- e-Label: On-screen e-Label embedded in software device (e.g. About Box, power-on screen)

Other comments (if any):

2.5. If yes for Question #2, does e-Label waive regulatory requirements for physical label?

- Yes
- No (please direct to Question #3)

### Section 3. Opportunities and potential barriers

3. Choose all potential barriers, challenges and opportunities are faced in adopting e-Label and/or e-IFU as an alternative method to traditional physical labelling (select all applied and specify concerns)

- Healthcare professionals (specify concerns: [whether e-IFU and the authorized version of IFU are identical](#))
- Patients (specify concerns: [accessibility of e-IFU to home-use medical device user](#))
- Local / International (Global) Competent Authorities
- Regulations (specify concerns: [Currently, Article 14 to 17 of the Regulation for Registration of Medical Devices require manufacturers for Class II and III medical devices to submit the form for attaching outer box instruction label with all Chinese instruction leaflet catalogue packaging, and labelling, instructions for use in duplicate during product registration, therefore for product of medium to high risk, including IVD, their IFU and labelling has been approved by the regulatory authority before marketed, therefore there is important implication in how to verify the e-IFU and the authorized version of IFU are identical.](#))
- IT infrastructures
- Supply chain members - Manufacturers, Importers, and Distributors
- Others

#### **Section 4. Suggestions**

4. What should AHWP consider in the guidance for "e-IFU or e-Label as an alternate method for compliance to labelling requirement" to overcome potential barriers posed by different stakeholders: (select all applied and elaborate)
- Introduce New Regulations or modify the current regulation including estimated timeline of the regulation change
  - Limit the applicability scope to selected MD/IVD types, e.g. for professional users, for lay persons
  - Develop the guidance of website validation and management
  - Any other areas of consideration

# Tanzania

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## Section 1. Status on e-IFU

1. Is Medical Device IFU regulated in your country?

Yes

No (please direct to Question #2)

1.1. If yes for Question #1, please describe the definition of IFU and requirements on IFU including device scope and content under regulation.

We do not have a definition for IFU in our Guidelines for Medical Devices Registration but we have the requirement for IFU in the Section of Device Details of the Guidelines that is “Give a concise summary of information for safe use of the device including procedures, methods, frequency, duration, quantity and preparation to be followed.”

1.2. If yes for Question #1, does the content and the update of the content require approval by the Competent Authority before release?

Yes

No

1.3. If yes for Question #1, is there a difference of the regulatory control for IFU between medical devices and IVD medical devices?

Yes

No

1.4. If yes for Question #1, which of these IFU formats are allowed? (select all applied)

Physical IFU: Provided with the medical device

Physical IFU: Digital IFU provided with the medical device (CD, USB, DVD, etc.)

e-IFU: web-based e-IFU in electronic, not included with the medical device, but available to the customer at the time of use

e-IFU: On-screen e-IFU (connected to web, or embedded in software device)

Other comments (if any):

1.5. If yes for Question #1, does e-IFU waive regulatory requirements for physical IFU?

Yes

No (please direct to Question #2)

## Section 2. Status on e-Label

2. Is Medical Device Label regulated in your country?

Yes

No (please direct to Question #3)

2.1. If yes for Question #2, please describe the definition of Label and requirements on Label including device scope and content under regulation.

### Label

Means written, printed or graphic information provided upon the medical device itself. Where physical constraints prevent this happening, this term includes information provided on the packaging of each unit or on the packaging of multiple devices.

2.2. If yes for Question #2, does the content and the update of the content require approval by the Competent Authority before release?

Yes

No

2.3. If yes for Question #2, is there a difference of the regulatory control for Label between medical devices and IVD medical devices?

Yes

No

2.4. If yes for Question #2, which of these label formats are allowed? (select all applied)

Physical label: Provided with the medical device

Physical label: Digital label provided with the software medical device (label on jewel case of CD, USB, DVD, etc.)

e-Label: web-based e-Label in electronic, not included with the medical device, but available to the customer at the time of use

e-Label: On-screen e-Label embedded in software device (e.g. About Box, power-on screen)

Other comments (if any):

2.5. If yes for Question #2, does e-Label waive regulatory requirements for physical label?

Yes

No (please direct to Question #3)

### Section 3. Opportunities and potential barriers

3. Choose all potential barriers, challenges and opportunities are faced in adopting e-Label and/or e-IFU as an alternative method to traditional physical labelling (select all applied and specify concerns)
- Healthcare professionals (Language translation, network problem)
  - Patients (Language translation, network problem)
  - Local / International (Global) Competent Authorities (Applicants might not be able to meet the regulatory requirements)
  - Regulations (Might be stringent to our stakeholders)
  - IT infrastructures
  - Supply chain members - Manufacturers, Importers, and Distributors (Applicants might not be able to meet the regulatory requirements for the time been)
  - Others (specify concerns: e.g. language translation, caution health/safety hazards, or indication of the nominal frequency, etc.)

### Section 4. Suggestions

4. What should AHWP consider in the guidance for "e-IFU or e-Label as an alternate method for compliance to labelling requirement" to overcome potential barriers posed by different stakeholders: (select all applied and elaborate)
- Introduce New Regulations or modify the current regulation including estimated timeline of the regulation change
  - Limit the applicability scope to selected MD/IVD types, e.g. for professional users, for lay persons
  - Develop the guidance of website validation and management
  - Any other areas of consideration