



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

FINAL DOCUMENT

Title: Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)

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Preface

The document herein was produced by the Asian Harmonization Working Party (AHWP), a voluntary group of medical device regulators and industry from AHWP members in Asia and beyond. The document has been subject to consultation throughout its development.

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Introduction

Labelling is one of the most important factors for safe use of medical devices. With ever changing types of medical devices and technological advances such as Internet, an electronic format of labelling providing the same information, as provided traditionally by paper, has been introduced gradually.

Jurisdictions such as Australia, Canada, Europe, India, Japan, Kingdom of Saudi Arabia, Singapore, South Korea, and United States of America have adopted and implemented electronic format of instructions for use to enhance user access to important product information as well as to reduce regulatory burden on the medical device industry and to harmonize with these jurisdictions. According to AHWP Working Group (WG) 1 document published in 2017, most of AHWP Members have not introduced electronic instructions for use (eIFU). Working Group 1, 2 and 3 of the AHWP have prepared this guidance document. Comments or questions should be directed to the Chair of AHWP Work Group 1 whose contact details may be found on the AHWP web page (<http://www.ahwp.info/>).

Purpose

This document is to provide the general principles when the instructions for use (IFU) is provided in an electronic or online format.

Scope

This document applies to applicable medical devices and IVD medical devices intended to be used by professional users.

Regardless of provision of eIFU, applicable regulatory requirements regarding labelling must be followed.

Electronic label is out of scope of this document.

References

- AHWP/WG1-WG2/F001:2017 *Regulation and treatment of e-IFU and e-Label of Medical Devices-Review of International Practice*
- AHWP/WG2/F001:2018 *Labelling for In Vitro Diagnostic Medical Devices*
- IMDRF/GRRP WG/N52 Final: 2019 *Principles of Labelling for Medical Devices and IVD Medical Devices*

- GHTF/SG1/N70:2011 *Label and Instructions for Use for Medical Devices*
- ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- November 2004 Medical Devices Technical Corrections Act (MDTCA) Expanded Authority for Electronic Labeling
- COMMISSION REGULATION (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices
- *REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC*
- *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU*
- TGA # D18-10786654 *Electronic Instructions for Use - eIFU*
- Gazette notification on electronic instructions for use by Ministry of Health and Family Welfare, India - G.S.R. 30(E) dated 15 January 2019

1 Definitions

1.1 Electronic Instructions for Use (eIFU)

Instructions for Use refers to general and technical information provided by the manufacturer to inform the device 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. (GHTF/SG1/N70:2011)

Electronic Instructions for Use (eIFU) 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) can also be referred to as "package insert" or "directions for use" and may also include "User Manual" or "Technical Manual."

Note 2: The eIFU 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.

1.2 Electronic Label

Label is 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. (GHTF/SG1/N70:2011)

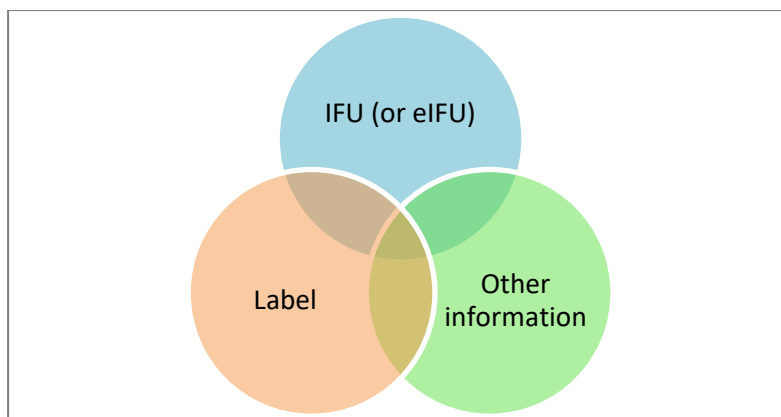
Electronic Label is the electronic version of labels.

1.3 Electronic Labelling

Labelling includes 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 (ISO 13485:2016).

Electronic Labelling refers to any form of labelling content provided in an electronically accessible form supplied by the manufacturer related to a medical device or IVD medical device. (IMDRF/GRRP WG/N52 FINAL:2019).

Figure 1. Labelling (or Electronic Labelling)



1.4 Lay User

Lay User refers to individual who does not have formal training in a relevant field or discipline.

NOTE 1: Principles for lay person(s) may also apply to self-testing for an IVD medical device.

NOTE 2: For an IVD medical device for self-collection or self-testing, a self-collector or self-tester is considered a lay user.

(IMDRF/GRRP WG/N52 Final: 2019)

1.5 Professional User

Professional User is someone who use a medical device during their professional healthcare activities and holds the required expertise for use through qualifications or training.

Professional User may include, but not limited to:

- a medical practitioner, a dentist, or any other kind of health care worker registered or accredited under the law or regulations of the applied jurisdiction, or
- a biomedical engineer, chiropractor, optometrist, orthodontist, osteopath, pharmacist, physiotherapist, podiatrist, prosthetist or rehabilitation engineer, etc. (TGA # D18-10786654)

2 Benefits of eIFU

The information contained within the IFU may be electronically provided as an acceptable alternative to be compliant with regulatory requirements. This not only reduces cost and environmental waste associated with paper-based IFUs, but also brings various advantages such as, but not limited to, the following:

- eIFU is sustainable and free from the risk of physical damage such as loss, wear, tearing, contamination, etc.
- eIFU content can be more timely updated to provide current and time sensitive information and/or important updated information related to product safety and/or performance.
- eIFU content may be accessed anytime and anywhere as it does not need to remain with the physical product, unlike a paper version.
- eIFU content is searchable, unlike paper-based IFUs, allowing the user to immediately find the specific information he or she is looking for in the language of choice.
- Provision of eIFU is the ecological approach by reducing the usage of physical means such as paper IFU or other physical media. eIFU will reduce the waste of providing multi-language IFUs as well as multiple copies of the same printed IFU.
- Professional users who repeatedly use the same medical devices will not need to refer to the same IFU provided with every single product unit.

On the other hand, any jurisdiction who takes eIFU into account may also consider the following:

- Lack of accessibility to Internet at the point of use/care,
- Lack of compatibility of the eIFU with the users' devices, and/or
- Cybersecurity risks.

3 Points to Consider in Providing eIFU

To offer the Instructions for Use in the electronic format, the following aspects must be considered.

3.1 Applicable Medical Devices

Medical devices including IVD medical devices intended to be used by professional users. Such devices include followings, but not limited to:

- Medical devices including IVD medical devices used by a professional user, or
- Medical devices including IVD medical devices only used in a healthcare facility.

Note: Paper or any other physical IFU shall be provided in the following cases.

- Paper or physical IFU shall be provided if the device is used by a lay user.
- Paper or physical IFU shall be provided upon request without undue delay or cost.

3.2 Information on eIFU

The eIFU should include all the information required for Paper IFU and comply with the regulations in the target regulatory jurisdiction. Additionally, eIFU should clearly state the following information.

- Version with effective date

Note: Version should be controlled by the quality management system. Change history should be documented and provided to the regulatory authority upon request. Obsolete versions of the current eIFU must remain accessible to the users where appropriate.

- Target regulatory jurisdictions where appropriate

3.3 Operating Environment to Display eIFU

eIFU shall be provided in a commonly used format that can be read with freely available software.

Note: It is recommended the distribution format is non-editable and searchable.

eIFU must be verified and validated to function in the operating environment as defined.

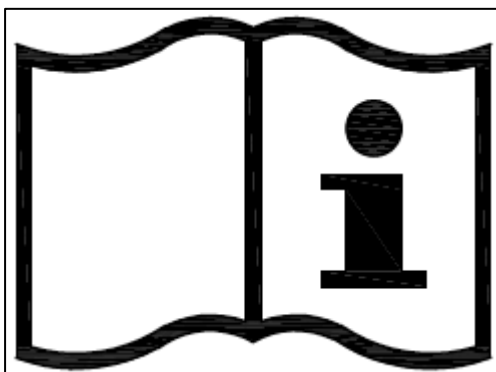
Note: eIFU shall be protected against hardware and software intrusion.

3.4 Indication of eIFU Provision

When only the eIFU is provided, the label on the device should indicate that the IFU is provided in an electronic form and how to access the eIFU.

Note: ISO 15223-1:2016 Medical devices (Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements) list symbols to be used as the indicator of eIFU provision.

Figure 2. ISO Symbol of eIFU Indicator



3.5 Risk Assessment and Quality Management System

Manufacturers must perform and document an appropriate risk assessment and change control for implementation of eIFU. In addition, procedures to maintain eIFU and revisions should be clearly documented within manufacturers' QMS.