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GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

PROPOSED DOCUMENT

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

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Working Group 1 - Pre-market: General MD
Working Group 2 - Pre-market: IVDD
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Contents

Preface

The document herein was produced by the Global Harmonization Working Party (GHWP), a voluntary group of medical device regulators and industry from GHWP 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, 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. Some of GHWP Members have introduced electronic instructions for use (eIFU). Working Group 1, 2 and 3 of the GHWP have prepared this guidance document. Comments or questions should be directed to the Chair of GHWP Work Group 1 whose contact details may be found on the GHWP web page (http://www.GHWP.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 intended to be used by professional users.
Note: The term “user” in this document refers to professional user.

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
- AHWP/WG3/F001:2016 Guidance document on Risk Categorisation of Software as a Medical Device
- IMDRF/GRRP WG/N52 Final: 2019 *Principles of Labelling for Medical Devices and IVD Medical Devices*
- IMDRF/SaMD WG/N10FINAL: 2013
- IMDRF/GRRP WG/N47FINAL:2018
- GHTF/SG1/N70:2011 *Label and Instructions for Use for Medical Devices*
- ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
- ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer
- ISO 15223-1:2021 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 IMPLEMENTING REGULATION (EU) 2021/2226
- *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*Electronic Instructions for Use - eIFU* as amended from time to time
- Gazette notification on electronic instructions for use by Ministry of Health and Family Welfare, India - G.S.R. 30(E) dated 15 January 2019
- MDS-REQ1 Requirements for Medical Device Listing and Marketing Authorization
- MFDS Guidance for Review and Approval of Medical Device Cybersecurity (13 July 2023)

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) may be referred to other terms. Examples are "package insert,""directions for use," "User Manual," "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

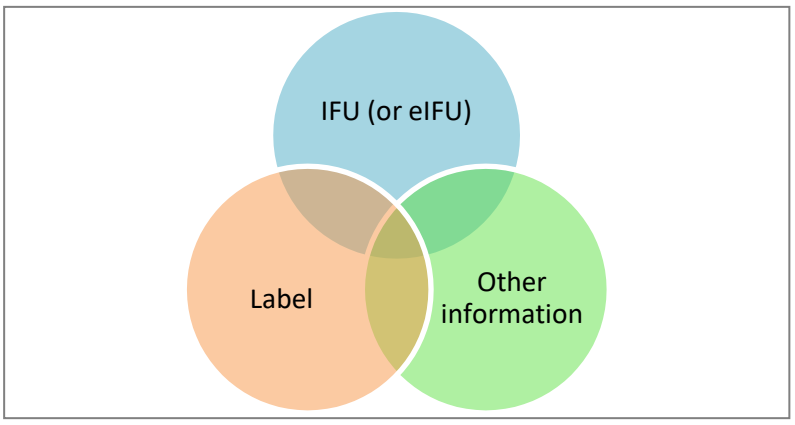
Label is written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices. (GHTF/SG1/N70:2011)*Electronic Label* is the electronic version of labels.

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 User

The person, professional or lay, who uses a medical device. The patient may be that user.
(IMDRF/GRRP WG/N52 FINAL:2019)

1.5 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)

1.6 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.

(TGA # D18-10786654)

1.7 Patient

An individual under the care of a healthcare provider who may benefit from the action of a medical device. A patient may also be a user of a medical device.

(IMDRF/GRRP WG/N52 FINAL:2019)]

1.8 Software as Medical Device (SaMD)

Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.

(AHWP/WG3/F001:2016)

1.9 Self-testing IVD Medical Device

An IVD medical device intended for use by a lay user who is responsible for collecting the data or specimen, by themselves and on themselves, relying solely on the instructions provided by the manufacturer. This use can also include performing the test and interpreting the results by themselves and on themselves.

(IMDRF/GRRP WG/N47FINAL:2018)

1.10 Device for Near-Patient Testing

Any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient by a health professional.

(REGULATION (EU) 2017/746 IVDR)

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.
- Utilizing electronic manuals instead of paper manuals conserves packaging space, facilitating streamlined product packaging and efficient storage in the supply chain. . eIFU content can be swiftly updated to disseminate current and time-sensitive information, including critical updates related to product safety and performance (e.g. as medical device software - including artificial intelligence-enabled medical devices)
- eIFU content may be accessed anytime and anywhere as it does not need to remain with the physical product, unlike a paper version, promoting user convenience and accessibility.
- eIFU content is searchable, unlike paper-based IFUs, enabling users to swiftly locate specific information.
- eIFU improves the readability of medical device manuals. Users can obtain and read electronic manuals through screen readers, networks, and mobile applications and can also adjust the font size and screen contrast according to their personal reading habits to improve the reading experience. Manufacturers can adopt more advanced interactive designs, such as animation or voice prompts.
- eIFU reduces the operating cost of the manufacturer and simplify the operation cost in terms of physical space, equipment, raw materials, and manpower. Eliminating manual operation process, reducing cost and minimizing human errors.eIFU makes the realization process more flexible and efficient, which can shorten the production cycle, accelerate product realization, and expedite time-to-market for approved products.
- Provision of eIFU is the ecological approach by reducing the usage of physical means such as paper IFU or other physical media. eIFU will diminish waste and the need for multi-language or redundant printed IFUs.
- Repeated users of medical devices should be able to conveniently access eIFUs, eliminating the need for repetitive reference to IFUs with each product unit.

3 Points to Consider in Providing eIFU

Instructions for Use in the electronic format shall be consistent with the content of the instructions for use in paper form. The following aspects must be considered.

3.1 Applicable Medical Devices

Applicable medical 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 1: Paper or physical IFU shall be provided for:

- Medical device used by a lay user, unless the medical device is SaMD with no physical hardware.
- Self-testing IVD medical device
- Near-patient testing products if required by local regulation.

Note 2: Paper or physical IFU shall be provided upon request without undue delay or cost.

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3.2 Provision of eIFU

The appropriateness of allowing the use of eIFU is dependent on situation-specific considerations related to the conditions of use within the target regulatory jurisdiction, including the following:

- Lack of accessibility to the internet at the point of use/care,

  Note: eIFU should be easily accessed and allow user to view the instruction at the time of device use.
- Lack of compatibility of the eIFU with the users' devices, and/or
- Cybersecurity risks (refer to later section)

3.3 Information on eIFU

The eIFU should include all the information required for Paper IFU and comply with the regulations in the relevant 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.
- Any unique device identifier information (e.g. UDI) that is required to be in the IFU by the relevant regulatory jurisdiction authority.

3.4 eIFU Format and Delivery Medium

- eIFU shall be provided in a commonly used format that can be read with freely available software. (e.g. PDF or Rich Text Format, etc.).

  Note: It is recommended the distribution format is non-editable and searchable.
- eIFU may be provided in a portable media (e.g. USB, CD, etc.) or by a URL/QR

Code to manufacturer's website where eIFU can be accessed and/or downloaded.

- eIFU may be provided preinstalled in the device. The accessibility and the consistent management of revision should be considered as the current version of eIFUs should be easily found.

3.5 Operating Environment to Display eIFU

Characteristics of the device's operating environment should be considered to make sure eIFU is displayed as intended.

Note: Backup mechanisms may be needed in the event of hardware or software fault or in case of foreseeable emergency situations.

3.6 Cybersecurity Risks

eIFU shall be sufficiently protected against hardware and software intrusion and these protections should be based on a risk analysis and mitigation plan that considers all potential cybersecurity risks to the eIFU, including authenticity, integrity, availability, confidentiality, and update processes. Manufacturers shall protect their website or database hosting eIFUs against unauthorized access and tampering of content. They shall also ensure that the server downtime and display errors are reduced as far as possible.

3.7 Indication of eIFU Provision

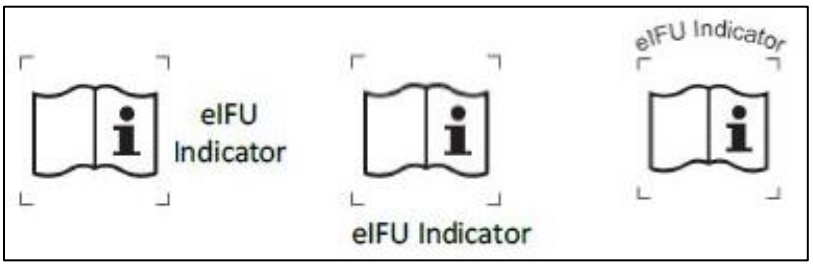
Each target regulatory jurisdiction shall have access to the current version of eIFU as applicable.

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

- This information could be provided on the packaging or on the device itself. If not applicable, it shall be provided in a paper document supplied with the device.

In the case of software, this information could be provided at the primary user interface.
Note: ISO 15223-1:2021 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. Examples of ISO Symbol of eIFU Indicator



3.8 Risk Assessment and Quality Management System

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