Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

eIFU: Requirement and Best Practices

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Johnson & Johnson

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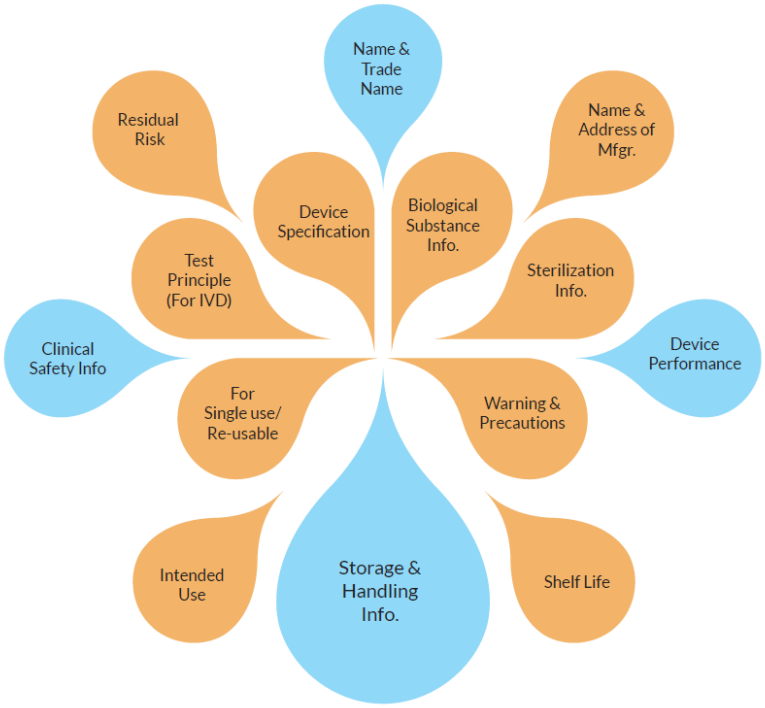
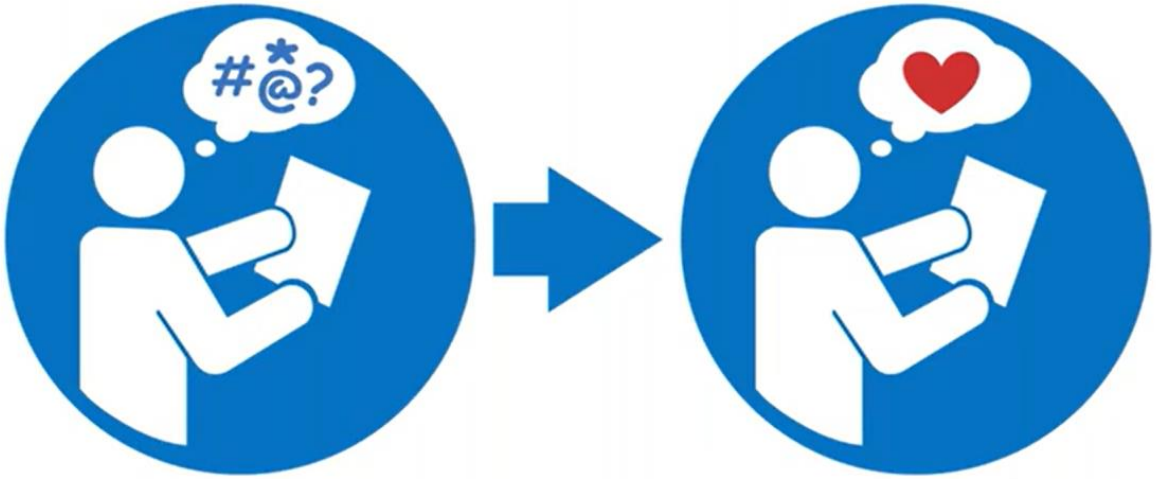
What?

- ***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 (***GHTF/SG1/N70:2011***)
- ***(GHTF) 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.
- 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.



Why: world without paper IFUs?

- Improved Readability & usability
- reducing the risks of error
- less environmental impact
- reduced costs & improve efficiency
- Improves Time to Market

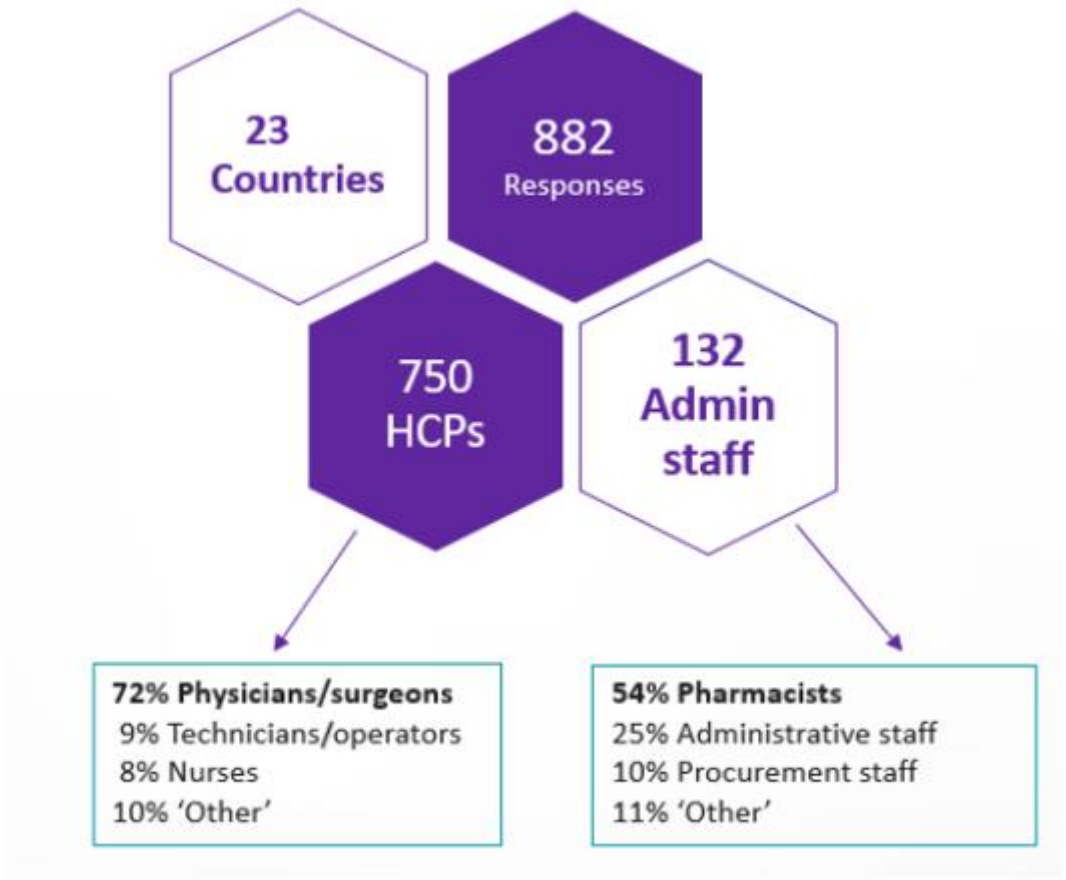


Innovation is changing our world

Current Approaches in established Jurisdictions

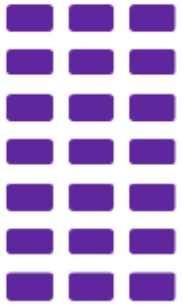
3 main approaches to applicability/ acceptability

- **either allowed for all** types of medical devices to replace the paper version of the IFU with an eIFU or **for none**
- eligible for devices limited to those intended for use **by professional users** and not for supply to the general public
- determine the applicability of an eIFU by the **type of device**
  - **implantable and active implantable** medical devices covered by Regulation (EU) 2017/745;
  - **fixed installed** devices covered by Regulation (EU) 2017/745;
  - medical devices and their accessories (covered by Regulation (EU) 2017/745) and **fitted with a built-in system** visually displaying the instructions for use



Clear messages of support for electronic IFU have emerged:

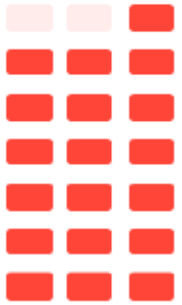
Key messages



>99%

Internet Access

The overwhelming majority of healthcare professionals who took the MedTech Europe survey does have access to internet at work: over **99%** said yes, while under 1% does not have internet access at work.



90%

Hospital admin staff prefers eIFU

Over **90%** of the hospital administrative staff/hospital pharmacists would prefer to have eIFU for medical devices. Only a little above 9% would not prefer this.

88%

HCPs prefer eIFU

Over **88%** of healthcare professionals would prefer to have the electronic IFU if available. Only around 12% prefer paper version.

Ref: MedTech Europe position paper ''Electronic Instruction for Use for all professional use Medical Devices"

Requirements

- a documented **risk assessment**.
- **language** in which the device is made available.
- system in place to provide IFU in **paper form at no additional cost** for the user.
- Ensure proper **design, usability, and functioning** of the eIFU and provide **verification and validation** evidence to this effect.
- Provide **information on software and hardware** requirements needed to display the eIFU.
- **Document Control** & system in-place to inform each user of the device thereof if a revision was necessary for safety reasons.
- all **historical issued electronic versions** of the IFU on the website.
- **indicate on the label** that IFU is supplied in electronic form instead of paper form.

Use of e-IFU Worldwide

USA

- General Program Memorandum **#G03-1** (MDUFMA), Dated: 31-Mar-2003:
- Section 206 of MDUFMA amended Section 502(f) of the Federal Food, Drug, and Cosmetic Act (the Act) to authorize the use of electronic labelling, rather than the traditional paper labelling, under specified circumstances.
- The 2004 Medical Devices Technical Corrections Act (MDTCA), P.L 108-214 **amended and expanded** the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).
  - Section 2(b)(2)(B)(i) extends the electronic labeling provision (section 502(f) of the FD&C Act)

    To
  - Prescription devices used by a health care professional, **regardless of the setting** in which the device is used.

Australia

Electronic Instructions for Use – e-IFU, For professional users of MDs (including IVDs) **Guidance, V 1.0**, Aug 2018: Eligible devices are limited to those intended for use by **professional users**, and not for supply to the general public

Use of e-IFU Worldwide

Canada

- File No. 15-107097-797 26-Jun-2015
- For devices that are not sold to the general public, this information may be provided as downloadable from the internet and/or on electronic data storage devices, such as compact disc, digital video disc or universal serial bus (USB) flash drive.

Brazil

- ANVISA Collegiate Board of Directors RDC 751/2022 Dated: Sep 15th, 2022 (previous provision on eIFU: Normative Instruction – IN No. 4, Article 2; 15 June 2012) Article 54
- The exclusive availability of non-printed format instructions for the following products is prohibited:

  I – health use equipment that has an indication of:

  a) domestic use in general, including those for use in home care service; and

  b) Lay operation, regardless of the place of use;

  II – health materials used by lay public

Use of e-IFU Worldwide

Japan

- The new Japanese regulation eliminates the ability to provide eIFU (previously called “Tempu Bunsho”) in physical format for professional users. The new law requires all IFUs to be provided in electronic-only format, uploaded and maintained on a regulator-owned application, accessible by all customers. This does not apply to patient IFUs.

Saudi Arabia

- MDS – G10: Guidance on Labelling Requirements for Medical Devices, Dated: 18-Jan-2015: Where the de

South Korea

- MFDS notification 2018-500. This notification amended the Medical Device Act to specifically call out that providing required labeling via the internet is permitted. No other requirements were included in the notification, but only products which are specifically permitted per the notification may be eLabeled. Home-use labeling may not be eLabeled

Use of e-IFU Worldwide

Singapore

- Singapore's labeling requirements are guided by **GN-23** (June 2018) 'Guidance on Labeling for Medical Devices'. This document notes that paper IFUs should be provided except where specified. Several additional requirements note that for eLabeling
  - IFU may be provided in paper or non-paper format for professional-use devices
  - When provided in a form other than paper, the customer must have instructions on how to view and access the IFU
  - The internet address must be clearly printed on the physical label of the device. The electronic labeling must be identical to what would be provided in paper, and what is submitted.

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Use of e-IFU Worldwide

Bahrain

Circular No. 2 (2021), Date: 17 January 2021

Subject: Using “Electronic IFU

To: all importers of medical devices and manufacturers

As per NHRA role in monitoring the import and marketing of medical devices in the Bahrain market and ensuring safety and public health protection. the authority would like to draw the attention of all importers of medical devices and manufacturers to the fact that in addition to the many benefits of using "Electronic IFU” including:

- Easy access to the latest information related to the use of the medical device.
- Searchable, which reduces search time for specific information.
- It offers more language options and the ability to enlarge text and image. However, the use of this type of IFU is limited only to professional users who receive training on the use of E-IFU and it is not permissible to use it by lay people in order to ensure the safety use of the medical device

Serbia

- Official Gazette of RS”, No. 105/2017, Article 93:
- In the case where exclusively healthcare professionals use the medical device and the accompanying equipment, or if their use is not foreseen by persons other than healthcare workers, the manufacturer may provide instructions for use in electronic form instead of in paper form

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GHWP's

Revisit 'Principles of Regulatory Requirements for eIFU: 2019'

Survey: User scope of eIFU, e-IFU Formats, Risk mitigation, QMS Requirements, hard Copy supply and equivalence, and content of e-IFU

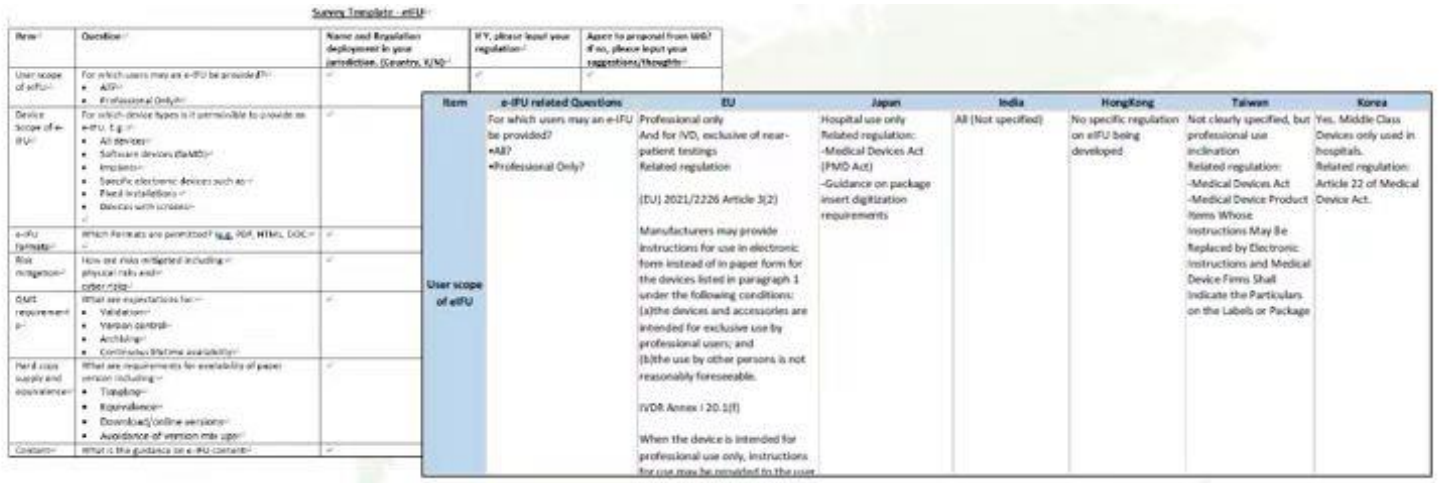
Call for Comments on the Proposed Document 'Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)'

Submitted by admin on Fri, 10/13/2023 - 15:27

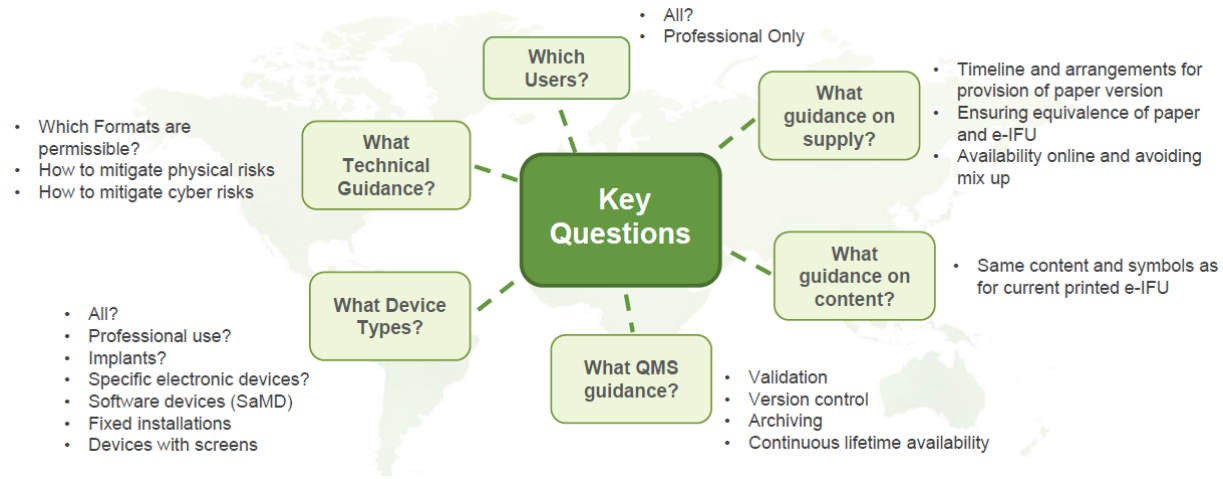
For your kind perusal, please find attached the WG1, WG2 & WG3 Proposed Document 'Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)'.

Kindly send your comments with the template attached to the GHWP Secretariat (secretariat@ghwp.info) on or before 20 November 2023 (Monday)12:00noon (GMT+8). Thank you.

Download file: GHWP-WG1-WG2-WG3-P002-2023 (Call for comments).pdf
GHWP Comments Template_1.pdf



Item	e-IFU related Questions	EU	Japan	India	HongKong	Taiwan	Korea
User scope of eIFU	For which users may an e-IFU be provided? •All? •Professional Only?	Professional only And for IVD, exclusive of near-patient testings Related regulation (EU) 2021/2226 Article 3(2) Manufacturers may provide instructions for use in electronic form instead of in paper form for the devices listed in paragraph 1 under the following conditions: (a)the devices and accessories are intended for exclusive use by professional users; and (b)the use by other persons is not reasonably foreseeable. IVDR Annex I 20.1(f) When the device is intended for professional use only, instructions for use may be provided to the user	Hospital use only Related regulation: -Medical Devices Act (PMD Act) -Guidance on package insert digitization requirements	All (Not specified)	No specific regulation on eIFU being developed	Not clearly specified, but professional use inclination Related regulation: -Medical Devices Act -Medical Device Product Items Whose Instructions May Be Replaced by Electronic Instructions and Medical Device Firms Shall Indicate the Particulars on the Labels or Package	Yes. Middle Class Devices only used in hospitals. Related regulation: Article 22 of Medical Device Act.



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Thank you!

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