Australian Government
Department of Health
Therapeutic Goods Administration

Electronic Instructions for Use - eIFU

For professional users of medical devices (including IVDs)

Version 1.0, August 2018

TGA Health Safety Regulation

The purpose of this guidance is to help manufacturers and sponsors understand how the TGA interprets regulations, and thus indicate how to comply.

This is a guide only, and manufacturers and sponsors are encouraged to familiarise themselves with the legislative and regulatory requirements in Australia. If necessary, seek professional advice as it is the responsibility of each manufacturer or sponsor to understand and comply with these requirements.

This document will evolve over time and updates and clarifications will be included as required. Feedback on the guidance is always welcome.

Contents

Introduction

This guidance is for manufacturers of medical devices who may be considering supplying the instructions for use of their device in an electronic or online format.

Note

Eligible devices are limited to those intended for use by **professional users**, and **not for supply to the general public**.

Based on feedback received from Australia's peak bodies for the medical device industry, the TGA has considered its position on the provision of medical device information using electronic means. In its deliberations, the TGA has also considered the positions of other similar regulators, e.g. Health Canada, the United States Food and Drug Administration and the European Commission, all members of the International Medical Device Regulators Forum (IMDRF).

In order to reduce regulatory burden on the Australian medical device industry, and to better align with other IMDRF regulators, the TGA now considers that in certain circumstances the provision of Instructions for Use (IFU) for medical devices may be undertaken electronically, either online through a manufacturer's website or via other electronic means.

Definitions

Instructions for Use (IFU)

Information provided by the manufacturer for the intended user detailing how the device can be used safely for its intended purpose.

The IFU may be referred to as **directions for use** in some international jurisdictions.

Note

Essential principle 13.4 of Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* prescribes specific information that must be included in the IFU for the purposes of supply in Australia.

Electronic IFU (eIFU)

Electronic instructions for use — instructions displayed in electronic form:

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

Note

The eIFU must be a complete representation of all the information required to be included in the IFU as specified in the essential principles.

Label

Means a display of printed information[1]:

- on or attached to the goods, or
- on or attached to a container or primary pack in which the goods are supplied, or
- supplied with such a container or pack.

Labelling

Labels and other information required to be provided with a medical device.

Health Professional

Includes a person who is[2]:

- a medical practitioner, a dentist or any other kind of health care worker registered under a law of a State or Territory, or
- a biomedical engineer, chiropractor, optometrist, orthodontist, osteopath, pharmacist, physiotherapist, podiatrist, prosthetist or rehabilitation engineer.

Professional User

A user, including a health professional, who uses a medical device in the course of their professional duties, and holds the required expertise for use through qualifications or training.

Information that must be provided with a medical device

Essential principle (EP) 13 of Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) sets out the requirements for the information that must be provided with a medical device. This information includes the label, the IFU, and (if applicable) the patient implant card and patient information leaflet.

Certain information (specified in EP 13.3) **must be provided with** a medical device. This is always the case; and it is not sufficient to provide this particular information through a website identified in the product labelling, or through other electronic means. In the case of implantable devices, this includes information developed for both the healthcare professional responsible for implantation, and the patient receiving the implant.

Provision of some information electronically

There is the potential for some of the other information that must be provided with a medical device (including IVD medical devices) to be provided electronically. EP 13.2 provides for the use of a printed document **or other appropriate media**, for the provision of IFU which are specified in EP 13.4, when it is **not practicable** to comply with the requirement for providing these directly on the device, or directly on the device packaging.

[1] *Therapeutic Goods Act 1989*, Chapter 3
[2] *Therapeutic Goods (Medical Devices) Regulations, 2002*, Regulation 1.3

The TGA considers that cases meeting the 'not practicable' test could include, for example:

- Providing the IFU to professional users, such as surgeons for implantable medical devices. It is not practicable to provide the IFU directly on the implantable device; and the IFU for an implantable device are also too lengthy and complex to be provided directly on the device packaging.
- Providing the IFU component for MR scanning of implantable medical devices with a device. It is not practicable for the same reasons stated above; and in addition, providing such information with an implantable medical device is not necessarily the most effective way to ensure it reaches the relevant healthcare practitioners. These may include radiologists, MRI technicians, and specialists who are unrelated to the device implantation, but may be recommending or conducting a MRI scan for a patient with an implanted device.

When it is not practicable to provide the IFU directly on the device or device packaging, the IFU may be provided in a printed document or other appropriate media, in accordance with EP 13.2.

The TGA considers that "other appropriate media" for proving the IFU as specified in EP 13.4 to professional users (not the general public) could include online through a website, or by other electronic means.

Requirements for the provision of eIFU

If a manufacturer chooses the electronic option for the provision of IFU to professional users, a number of requirements will apply. These may be reviewed during pre-market submissions for applications requesting the provision of electronic IFUs, during on-site audits, and/or through post-market reviews of devices that have been included in the ARTG with this allowance.

Users of eIFU

Eligible devices are limited to those intended for use by professional users, and not for supply to the general public (i.e. paper-form IFU is required and additional electronic IFU is optional for devices supplied to the general public).

Users should always have the choice to obtain the content of the eIFU in paper form on request, without undue delay or within the time period specified in the risk assessment, and free of charge.

Information in electronic IFUs

The electronic IFU must clearly state the date of release, and target regulatory jurisdiction and should be version controlled. Changes implemented in each version (i.e. version history) should be documented for review by the TGA if requested. For online IFUs, obsolete versions of the IFU must remain accessible to the public where appropriate.

Information in the electronic IFU must include all items specified in essential principle 13.4 of the MD Regulations, and must comply with all other applicable Australian laws (for example, warranty disclaimers, that are misleading with regards to a manufacturer's obligations for damages related to a device, are not allowed under the Australian Competition and *Consumer Act 2010*).

Any information on software and hardware requirements needed to display the instructions for use must be readily available.

The design and functioning of any instructions for use in electronic form must be verified to ensure the electronic document opens and functions correctly.

Time period IFU to remain available

An IFU supplied to users in electronic form must remain available to the users for a period of at least 5 years or the lifetime of the device (whichever is longer); and this period shall continue to apply after the last device has been manufactured. For implantable medical devices, an IFU supplied in electronic form must remain available to users for at least 15 years or the lifetime of the device (whichever is longer); and this period shall continue to apply after the last device has been manufactured.

The electronic IFU for obsolete devices must remain available during the document retention period as required above and clearly indicate the dates during which the obsolete device was supplied and when the electronic IFU becomes unavailable to the users.

IFUs exclusively available via a website

For IFUs that are exclusively available via a website:

- The IFU must be easy to locate from the manufacturer's homepage or a simple web search (e.g. – manufacturer name + device name + IFU).
- The IFU should be readily accessible and should not require the creation of an online account or password.
- The IFU approved for Australia should be readily identified as such.
- If the IFU for a device is live online prior to the device's inclusion in the Australian Register of Therapeutic Goods (ARTG), the manufacturer must identify the device as not available in Australia.

Indication that IFU is supplied in electronic form

The physical information provided with the device must clearly indicate that the instructions for use of the device are supplied in electronic form instead of in paper form; and where relevant, the URL (Uniform Resource Locator) indicating the web address with clear navigation to where the eIFU is located on the internet should be provided to users.

For medical devices fitted with a built-in system visually displaying the instructions for use, the display of the instructions for use must not impede the safe use of the device, in particular life-monitoring or life-supporting functions.

Manufacturers' QMS

- As with paper-form IFUs, electronic IFUs for eligible devices must not undergo substantial change without notification to the TGA for assessment prior to the change. Safety related changes should be managed through the Uniform Recall Procedure for Therapeutic Goods to ensure appropriate notification is provided to affected users.

Note

Examples of substantial changes to IFU can be found in the guidance document Substantial changes affecting a TGA conformity assessment certificate & Transfers of certificates

- Manufacturers must conduct and document a risk analysis for implementation of electronic IFUs and maintain records of this analysis. Specific points to address include:
  - Does the intended user have the required level of experience and the means to use the electronic IFU (e.g. a computer with internet access at or near the device's point of use, CD/DVD Drive or a compatible web-browser)?
  - Are there back-up methods for accessing the electronic/hard-copy IFU?
  - Are there processes in place to ensure ongoing security of electronic IFU?
- Manufacturers must have defined procedures and processes for the establishment and revisions to electronic documents.

IVDs

IFUs may not be supplied exclusively in electronic form for IVD medical devices intended for near-patient testing (i.e. at the point of care); paper-form IFU must also be provided.

Where medical devices are supplied sterile

For medical devices that are supplied sterile, if removal of the paper-form of an IFU from inside a sterile packaging unit in favour of supplying an eIFU could result in changes to the bioburden and sterilisation dosing requirements established for the device, the manufacturer must have clearly considered the impact of the changes on sterilisation processes and address accordingly.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch, Therapeutic Goods Administration	15/08/2018

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