Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Instructions for Use for Medical Devices

Consultation on availability of instructions for use in more flexible formats

Version 1.0, April 2024

Contents

Introduction

The Therapeutic Goods Administration (TGA) is the Australian government authority responsible for the regulation of therapeutic goods including medicines, medical devices, and biologicals to help Australians stay healthy and safe.

The Therapeutic Goods Act 1989 and associated supporting legislation set out the regulatory requirements for medical devices. This includes what information must be provided with a medical device and in what format, including the product label and instructions for use (IFU). The IFU is the information provided by the manufacturer for the intended user detailing how the device can be used safely for its intended purpose. For implanted medical devices, further information is available to patients in the form of patient information leaflets (PILs) and patient implant cards (PICs).

The TGA has received feedback from Australia's peak bodies for the medical device industry on how IFU are provided, and whether IFU should be provided in more flexible formats, e.g., electronically. Global developments have indicated that the timing for this review is appropriate as:

- use of electronic communication and digital health literacy continues to increase,
- other comparable jurisdictions have moved to accept electronic IFU (eIFU) in a range of circumstances, and
- there may be additional benefits through digitalisation and data interoperability.

There are anticipated benefits for a range of stakeholders as:

- industry and consumers have indicated that it is important to cater for different consumer preferences,
- patients can access up-to-date information when needed if they have concerns about their medical devices,
- there may be better health outcomes through appropriate use of medical devices, and
- eIFU may reduce regulatory burdens and costs.

Definitions

Instructions for Use (IFU)

Instructions for Use (IFU) means the information provided by the manufacturer for the intended user which details how the device can be used safely for its intended purpose. This may be referred to as directions for use in some international jurisdictions.

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

Electronic Instructions for Use (eIFU)

Electronic Instructions for Use (eIFU) means the information or instructions displayed in electronic form, such as:

by the device (“help” systems, or graphical user interface (GUI)-based dialogues),

contained in portable electronic storage media (such as a USB) supplied by the manufacturer together with the device,

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 EP 13.4.

Professional user

Professional user means 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.

Health professional

Health professional includes but is not limited to a person who is:

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

In vitro diagnostic medical device (IVD)

In vitro diagnostic medical device (IVD) means a medical device if it is a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with other diagnostic goods for in vitro use. It must be intended by the manufacturer to be used in vitro for the examination of specimens derived from the human body, solely or principally for the purpose of giving information about a physiological or pathological state, a congenital abnormality or to determine safety and compatibility with a potential recipient, or to monitor therapeutic measures.

Essential Principles (EP)

Essential Principles (EP) are safety and performance requirements for medical devices, including in vitro diagnostic (IVD) devices.

Consumer medical device

Consumer medical device means a consumer facing medical device that is sold over the counter directly to users/public at non-speciality retail settings. They are for use by consumers in non-clinical environments. Examples include thermometers, home use blood pressure monitors and blood glucose monitors.

EU MDR

EU MDR means The European Union Medical Device Regulation (EU MDR) or MDR is a set of regulations that govern the clinical investigation, production and distribution of medical devices in Europe.

Legislative framework

The Essential Principles (EP) are set out within the Medical Device (MD) Regulations and specify requirements a medical device must meet in relation to development, safety and use of the device.

EP 13 of the MD Regulations sets out the requirements for the information that must be provided with a medical device including the product label and IFU.

EP 13.2 provides that information (including IFU) must be:

- provided on the medical device

but if this is not practicable

- provided on the packaging of the medical device

but if this is not practicable

- provided on a leaflet or other appropriate media supplied with the medical device.

EP 13.4 specifies the information that must be provided in the IFU.

The IFU must support safe use of the medical device, but the safety of the device must not rely on the IFU alone.

Discussion

Current requirements

Currently, IFU must be provided with the medical device to enable its safe and appropriate use. Where it is not practicable to comply with the requirement for providing IFU directly on the device, IFU can be provided directly on the device packaging, or on a leaflet or other appropriate media supplied with the medical device.

The provision of eIFU is allowed only under very specific circumstances. For medical devices that are limited to use by professional users only and where it is not practicable to provide the IFU directly on the device or the device packaging, the TGA considers it acceptable for the IFU to be provided electronically. Example of such devices include implantable medical devices, where it is not practicable to provide the IFU directly on the implantable device and the IFU for an implantable device is too lengthy and complex to be provided directly on the device packaging. Guidance is available at *Electronic Instructions for Use - eIFU: For professional users of medical devices (including IVDs)*.

In vitro diagnostic (IVD) medical devices

The same requirements apply for in vitro diagnostic (IVD) medical devices.

For COVID-19 Rapid Antigen Self-Tests (RAT) self-testing devices, conditions were applied to mandate the provision of IFU on the supplier's website, in addition to paper IFU. This was particularly helpful when customers bought kits with large pack sizes (e.g., 20 kits). As eIFU can be updated far more quickly than paper IFU, it was very useful to update information on frequently asked questions and performance for the most recent COVID variants. Manufacturers also had the opportunity to communicate instructions in a variety of electronic formats including animations, videos, voiceovers, and links to helpful resources on their website.

Changes for IFU

In Australia, any changes to the provisions of IFU for medical devices will need to take into consideration the international and domestic landscape, such as:

- *global convergence* - Australia has a small market share and must balance the impact of any localised regulatory change against what is happening in the larger global markets, especially those we most frequently trade with. Changes must be strategically aligned as well as fit for purpose in the Australian context,
- *digital access and digital literacy* – some consumers of medical devices may have limited access to digital information or inadequate digital literacy skills, and
- *interest vs uptake* - while the benefits and interest in digitisation may be high, uptake could be patchy and alternative options should remain available through transition, or in cases of system failure.

Example

You have previously purchased a home-use pulse oximeter from your local pharmacy and have misplaced the IFU.

If the product has an online instructions manual, you can go online and immediately read and understand how to use the product.

If the product does not have an online instructions manual, you will need to contact the company and wait for a paper instructions manual to be mailed to you or go back to your local pharmacy to seek assistance.

International context

The TGA continues to align Australian medical device regulations, where possible and appropriate, with the European Union Medical Devices Regulation (EU MDR). It is noted that current EU requirements for IFU are similar to Australian requirements, with the provision of eIFU for professional users under specific circumstances. However, there are requirements that manufacturers must meet, including:

- risk assessments
- labelling
- storage requirements, such as maintaining current and historical eIFU on their website for more than 15 years.

Most of the international requirements including the EU MDR requirements also align with the International Standard, ISO 20417 Medical Devices – Information to be supplied by the manufacturer (the Standard). The Standard serves as a central source for common applicable requirements such as for e-documentation. This includes availability of eIFU on manufacturers website, if they have a website, the eIFU should be easy to view, latest version should be accessible and paper format of the eIFU must be available where required.

Provision of eIFU across jurisdictions

Currently, Australia's requirements for eIFU for professional users align with the EU, USA, and Canada, with the EU having additional requirements for use and storage of eIFU, including risk assessments and maintaining eIFU for minimum time periods.

However, other countries such as the UK, Japan, Singapore, and South Korea allow eIFU for both professional and consumer users as indicated in the table below.

Country	eIFU provided	Users	Requirements
AUS	Yes for: (a) active implantable medical devices and their accessories (b) implantable medical devices and their accessories (c) fixed installed medical devices (d) medical devices and their accessories fitted with a built-in system visually displaying the Instructions for Use (e) standalone software.	Professional users	
EUROPE	Yes for: (a) implantable and active implantable medical devices and their accessories covered by Regulation (EU) 2017/745 (b) fixed installed medical devices and their accessories covered by Regulation (EU) 2017/745	Professional users only for a, b and c, consumer and professional users for d.	Risk assessment to be undertaken. Label to indicate that the IFU is supplied electronically, rather than paper. Paper must be available. Must maintain

Country	eIFU provided	Users	Requirements
	(c) medical devices and their accessories covered by Regulation (EU) 2017/745 and fitted with a built-in system visually displaying the Instructions for Use (d) software covered by Regulation (EU) 2017/745.		current and historical eIFU on their website for more than 15 years.
EUROPE In Vitro Diagnostics	For in vitro diagnostic medical devices (IVDs): When the device is intended for professional use only, Instructions for Use may be provided to the user in non-paper format (e.g., electronic), except when the device is intended for near-patient testing.	Professional users.	
USA	Yes for: a) electronic products b) prescription devices intended for use in health care facilities or by a health care professional c) in vitro diagnostic devices intended for use by health care professionals or in blood establishments.	Professional users.	Paper version upon request.
Canada	Yes, except for: a) custom-made medical devices b) special assess or investigational provisions.	Professional users	Must be in both official languages – English, French.
UK	Yes for: a) active implantable medical devices and their accessories b) implantable medical devices and their accessories c) fixed installed medical devices d) medical devices and their accessories fitted with a built-in system visually displaying the Instructions for Use e) standalone software covered by the UK MDR 2002. (f) IVDs, except for near-patient test IVD devices.	Professional users and consumers if the device is for professional user as well as consumer.	Risk assessment to be undertaken.
Japan	Yes. eIFU exclusively required.	Professional users and consumers provided with eIFU as well as paper IFU.	Pharmaceuticals and Medical Devices Agency (PMDA) (regulator) maintains website database with mobile phone app downloadable for free.

Country	eIFU provided	Users	Requirements
Singapore	Yes	Professional users and consumers if it is medical device software.	Legislation states IFU may not be needed or can be abbreviated for low-moderate risk devices.
South Korea	Yes	Professional users and consumers.	Unique Device Identifier (UDI) in use. Integrated database maintained by regulator; legislation indicates IFU to be stored here.

eIFU in Australia

There are some indications that Australian users could benefit from eIFU.

Following public consultation in 2021 in relation to patient information materials (PILs and PICs), almost all respondents, including consumers, agreed with the proposal for providing the information in a range of formats. This would allow information to be recorded in electronic formats such as electronic patient records and MyHealth records.

Therefore, requirements for patient information materials have changed to allow flexibility in formats. The TGA does not prescribe the matter in which these leaflets must be provided but expects sponsors and manufacturers to ensure the leaflets can be:

- readily and easily accessed by healthcare professionals and consumers,
- can be accessed free of charge, and
- are available as early as possible to inform discussions and treatments.

Potential consumer benefits should this be extended to eIFU include:

- access to the latest IFU including any important safety updates or recall information,
- confidence that users have accurate and timely information throughout their use of the medical device, as manufacturers can correct information or improve instructions as needed,
- ability to customise information to suit their needs and preferences, making use of the latest technologies such as:
    - interactive tools
    - multi-language settings
    - text to voice functions
    - options to select the audience – child/adult, consumer, carer, health professional, and
- potential to integrate with other technologies as they continue to develop.

However, the Australian Digital Inclusion Index (ADII), a relative measure of inclusion across 3 dimensions of access, affordability and digital ability, shows that major barriers continue to be language and adequate access to digital technology and information.

Example: Possible use of an eIFU for consumer medical devices

You just got home with your new continuous glucose monitor but you accidently threw out the instructions. It is ok though - the website for the eIFU is on the actual device itself.

You can look up the instructions online, bookmark the website and find out any information on how to use the device immediately.

You can also read the instructions in different languages or larger font that suits your needs.

This consultation

Several factors need to be considered when deciding if change is needed for IFU and what successful change would look like. Any change to current regulatory activity should strengthen regulatory safeguards to help keep Australians stay healthy and safe without introducing unmitigated risk and/or unnecessary resource burden.

Change to current requirements

Currently, an IFU must be on the device, its packaging, or an IFU leaflet in paper form or other appropriate media must be provided with medical devices.

eIFU are limited to professional users under specific circumstances.

Example: Current use of an eIFU for professional user

Knee replacement components – these devices are for use by a health professional, and the IFU are too lengthy and complex to be provided directly on the device packaging. Therefore, it may be more appropriate for an eIFU to be supplied in this circumstance.

Maintaining current requirements could have the following benefits:

Potential benefits	Potential impact if no change
• Familiar process for manufacturers and suppliers. • eIFU available for some medical devices for professional uses (under specific circumstances). • IFU supplied with product at point of purchase.	• Industry has indicated a desire to use eIFU. • No savings on industry costs or environmental impost. • No improvement to consumer benefits and accessibility. • Limited space on paper/packaging to provide comprehensive IFU and/or in various languages. • Mistakes in packaging can occur. • Medical devices with extended shelf life/use span may be in use with outdated IFU. • Recall/compliance activity that includes changes to IFU is unlikely to flow through to all users.

Potential benefits	Potential impact if no change
	• Consumers may not have access to the most up to date IFU.

Consultation question 1

Do the current requirements for providing IFU for medical devices need to change? Why or why not?

eIFU used for a greater range of medical devices

Currently, EP 13.2 guides the use of a printed document or other appropriate media, for the provision of IFU in circumstances when it is not practicable to comply with the requirement for providing these directly on the device, or directly on the device packaging.

Electronic information could be provided in a variety of ways such as:

- interactive tools
- multi-language settings
- text to voice functions
- options to select the audience – child/adult, consumer, carer, or health professional.

Example: Flexibility of eIFU for professional users

Pacemaker – these devices are for use by a health professional, and the IFU are too lengthy and complex to be provided directly on the device packaging. A health professional could look up the IFU on a website and follow the instructions. Further, if there have been any changes or updates to the IFU, the health professional will have immediate access to these changes.

Should manufacturers have the option of providing eIFU with their device, it is expected that they would still be required to supply paper IFU without undue delay and free of charge upon request.

The following table outlines some of the potential benefits and impact of allowing the provision of eIFU to a broader range of circumstances and medical device types for professional users:

Potential benefits	Potential impact of not allowing broader provision of eIFU
• Industry has indicated a desire to use eIFU • eIFU would become available for a greater range of medical devices • Information about use can be updated and disseminated more quickly online • Professional users would have access to eIFU for a greater range of medical devices and circumstances • IFU would continue to be supplied with product at point of purchase.	• Changes required for industry • No improvement to consumer benefits and accessibility • Limited space on paper/packaging to provide comprehensive IFU and/or in various languages • IFU may not be updated • eIFU may not be updated as required

Potential benefits	Potential impact of not allowing broader provision of eIFU
	• Medical devices with extended shelf life/use span may be in use with outdated IFU. • The requirement for manufacturers to supply paper IFU upon request may not work well in the IVD space. If an end user were to test for COVID-19 and require a paper IFU, the delay would change the clinical situation and make testing ineffective.

Consultation question 2

Should eIFU be allowed for a greater range of medical devices for professional users? Why or why not? What other circumstances should apply?

eIFU available for consumer medical devices

Currently, Australia, the EU, USA, and Canada allow for eIFU for professional users in limited circumstances. Countries such as the UK, Singapore, Japan, and South Korea allow eIFU for consumers.

Providing eIFU for consumers and professional users has the potential to provide benefits for them as well as industry.

As above, electronic information could be provided in a variety of ways to cater to the audience. Should manufacturers have the option of providing eIFU with their device, it is expected that they would still be required to supply paper IFU without undue delay and free of charge upon request.

Overall, the objective would be to ensure that the user can easily and practically access an IFU for their medical device in paper format if this is their preference or if they are unable to access digital information.

Example: Possible use of an eIFU for consumer medical devices

Blood pressure monitors – these devices can be purchased by consumers to enable them to measure their blood pressure at home. Your new blood pressure machine has just arrived.

On the machine is a website link so that you can look up the instructions on how to use the machine.

The manufacturer recently made a change to the instructions, however, as they are online, the change is already made and the IFU is up to date.

The following table outlines some of the potential benefits and impact of allowing the provision of eIFU to consumers:

Potential benefits	Potential impact of not allowing broader provision of eIFU
• Manufacturers can correct information or improve instructions quickly	• Changes required for industry

Potential benefits	Potential impact of not allowing broader provision of eIFU
• Safety updates and recall information can be provided immediately to eIFU • Increased consumer and patient access to information • Information could be customised to suit customer needs and preferences • Information could be accessible if paper IFU are misplaced or lost • There is potential to integrate with other technologies as they continue to develop • Australian alignment with some countries for the provision of eIFU to consumers • Prior access to this information can be useful for consumers in purchasing decisions.	• There may be barriers to accessing digital technologies and digital information • Australia would not be in alignment with the EU MDR • Jurisdictions such as the EU, USA, and Canada currently allow provision of eIFU for professional users only • The additional step of accessing paper IFU vs eIFU supplied with the device may possibly act as a disincentive for some consumers to access and read the instructions • Some medical devices may always benefit from paper IFU e.g., those used in emergency situations such as defibrillators • While the manufacturer could provide a paper version upon request, this will take time.

Consultation question 3

Should eIFU be available for consumer medical devices? Why or why not?

Consultation question 4

Are there specific types of medical devices that should be provided with an eIFU? Please explain.

Consultation question 5

Are there specific types of medical devices that should not be provided with an eIFU? Please explain.

Consultation question 6

If an eIFU is provided for a medical device, how long should eIFU be accessible for? Please explain.

eIFU storage and availability

It would be expected that eIFU are accessible for a number of years after provision and be updated with important or changing information in regard to the medical device.

The following economic, social, and environmental potential benefits and impact have been identified for a centralised, national eIFU database:

Potential benefits	Potential impact of eIFU storage
• eIFU could be stored in a database developed and maintained by TGA	• The eIFU database becomes the centralised source of information

Potential benefits	Potential impact of eIFU storage
• Improved user access to information • Consumers could access eIFU through the TGA's database, without needing to reach out to individual sponsors and manufacturers • Manufacturers would not need to develop or maintain separate databases for users to access.	• There may be concerns about commercially sensitive information being widely available • This database would require ongoing maintenance to ensure it continues to provide the required functionality over time • A back up alternative will need to be in place in cases of system failure.

Consultation question 7

How do you think eIFU should be stored and accessed?

Requirements for the provision of eIFU

Where a manufacturer is wanting to supply an eIFU with their medical device, they will need to meet several requirements. These requirements may include:

- undertake risk analysis that demonstrates user safety is upheld for medical devices intended for consumer use,
- provide clear information on how to access eIFU with the device,
- ensure the information contained in the eIFU is the same as that present in paper form, meeting EP13 requirements,
- have a backup or alternative method to access IFU should there be a system failure, including ability for consumer to contact the manufacturer if required via a phone number,
- provide contact details and fulfil consumer requests for IFU in paper form,
- ensure timely distribution of new information,
- maintain appropriate version control with documented changes and version history,
- meet recordkeeping requirements aligned with current documentation retention requirements, and
- where online eIFU are used:
    - they should be available on the manufacturer's website and easily searchable via product description or code
    - they should be available via a database maintained by the TGA.

      Note: TGA currently maintains various datasets available via the TGA website. eIFU could be linked to an existing database.

Consultation question 8

Do you agree with the mentioned above requirements for supply of eIFU that manufacturers must meet? Why or why not?

Consultation question 9

Are there any additional requirements for supply of eIFU that manufacturers must meet? Please explain.

Regulatory note

The legislation may need to be revised upon consideration of any changes to the provisions of IFU for medical devices.

Consultation

We invite your comments on issues associated with provision of IFU for medical devices. We are seeking your feedback on the suitability and potential impact that any proposed changes will have on you, your organisation and/or other medical device users.

How to respond

We have posed questions within this discussion paper to help guide your feedback. You can also give us any additional comments and attach a separate response document if you wish. You do not have to answer all the questions, and none are compulsory.

You can provide your response:

- By submitting your views via the link below – this will step you through our questions https://consultations.tga.gov.au/medical-devices-and-product-quality-division/instructions-for-use-ifu-for-medical-devices
- By downloading the full discussion paper and uploading your own response document on the final page of the link above.

Privacy and your personal information

We collect your personal information in this submission to:

- Contact you if we need to seek clarification of issues raised in your submission or to check whether you consent to certain information that you have provided being made publicly available, and
- Help provide context about your submission (e.g., to determine whether you are an individual or a director of a company or representing an interest group).

We may disclose your name, work title, company, and submission on the Internet (i.e. make this information publicly available) with your consent. You may specify whether there is anything in your submission which you would prefer to not be published online (e.g., names, email addresses, proprietary information) by:

- Providing an additional, redacted copy of your submission,
- Providing details of content not to be published e.g. “Do not publish pages 3-5”, “Please redact contact details”, and
- Identifying any text within your submission to remain confidential by having it clearly marked 'IN CONFIDENCE' and highlighted in grey.

Do not include personal information about other individuals in the body of your submission. Personal information in this context means information or an opinion about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion. The TGA will not publish personal information about you/others without your/their consent unless authorised or required by law.

Response timeframe

- This paper opened on 15 April 2024.
- Interested parties should respond by close of business on 28 May 2024. Late submissions after this date may not be considered.
- Following consideration of submissions, summaries of this discussion will be published to the Consultation Hub web page.

Contact us

Contact devicereforms@tga.gov.au if you have any questions about submissions.

Version history

Version	Description of change	Author	Effective date
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Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
Web: tga.gov.au

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