Medicines Australia | Better health through research and innovation

4 June 2024

Therapeutic Goods Administration (TGA)

Australian Government, Department of Health and Aged Care

Via: TGA consultation portal

To whom it may concern,

Re: Instructions for Use for Medical Devices - TGA Consultation on availability of instructions for use in more flexible formats

Medicines Australia welcomes the opportunity to provide feedback on the TGA consultation paper on the availability of instructions for use (IFU) in more flexible formats.

Medicines Australia is the peak body representing the innovative, research-based, medicines industry in Australia. However, many of our members are also the sponsors of medical devices and in vitro diagnostics (IVDs) so this consultation paper has direct bearing on them.

Our position

Medicines Australia agrees with the TGA's proposal to give medical device and IVD sponsors the option of providing electronic Instructions for Use (eIFU) for the end-user. We believe that it is important for it to remain optional for sponsors, as the introduction of (or full transition to) eIFU formats and business processes would come with certain risks and costs to sponsors. Sponsors may need to invest in new digital infrastructures, introduce new processes and undertake training to ensure their eIFU document remain compliant with regulatory requirements in Australia (and possibly overseas) and that appropriate safeguards are in place to protect the information.

However, despite these challenges, we agree that making IFU accessible electronically will benefit consumers and professionals by offering an increasingly favoured means of accessing the information. Electronic formats offer additional benefits including interactive features such as video instructions, animations and/or hyperlinks which can make them more user-friendly and easier to understand than hardcopy formats (e.g paper based and/or instructions on the device). Moreover, it would bring the changes proposed by the TGA in this consultation paper for IFU more closely into line with the requirements for medicine Product Information (PI) and Consumer Medicine Information (CMI) documents, which are already provided to the TGA electronically. Hence, it is not difficult to see that on the whole, eIFUs would be a more convenient, efficient, and sustainable way to provide instructions for the use of medical devices.

Consultation question 1 - Do the current requirements for providing IFU for medical devices need to change? Why or why not

Medicines Australia agrees that the current requirements for providing IFU should be modernised to give sponsors the option of providing IFU in an electronic format for professionals (not just in limited circumstances as is currently the case) and expanded to cover consumers. The TGA cites many reasons why such a move is needed, which we agree with.

If eIFU is expanded to a wider category of users and uses, the TGA should maintain its position to not prescribe the manner in which the information is provided, consistent with current requirements for provision of patient information materials. It will be important however that the TGA continues to ensure accessibility and currency requirements are met for the eIFU.

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?
In our members' experience, health care professionals have already adopted electronic media as a preferred means of fast, direct access to the latest information regarding products and services. It is therefore timely that regulatory frameworks and infrastructure are updated to reflect expectations of the community on how information is provided. Medicines Australia believes that an eIFU should be allowed for a greater range of medical devices for professionals and where the safe and proper use of the medical device can be safeguarded.

Consultation question 3 Should eIFU be available for consumer medical devices? Why or why not?
As the consultation paper has alluded to, consumers are increasingly accessing health and other consumer related information digitally and extending eIFUs to consumer medical devices is a natural step. Medicines Australia believes that an eIFU should be allowed for a greater range of medical devices for consumers and where the safe and proper use of the medical device can be safeguarded.

Consultation question 4 Are there specific types of medical devices that should be provided with an eIFU? Please explain.
Medicines Australia is of the general view that whether a specific medical device should be provided with an eIFU should be based on the level of risk to benefit. Our members, many of whom are global companies, will regularly engage with overseas regulators. We therefore support any efforts to align with requirements of overseas regulators and international standards.

Consultation question 5 Are there specific types of medical devices that should not be provided with an eIFU? Please explain.
Again, we believe the level of risk to benefit should be taken to justify a decision to not provide an eIFU.

Consultation question 6 If an eIFU is provided for a medical device, how long should eIFU be accessible for? Please explain.
For the lifecycle of the product.

Consultation question 7. How do you think eIFU should be stored and accessed?
Electronic PI's and CMI's for prescription medicines are currently required to be stored and accessed via the TGA website and these are limited to static document format (ie. "pdf" format). We understand that product information for many medical devices is currently stored and accessed exclusively via the manufacturer's website, unlike that of prescription medicines.
We note that the consultation paper proposes the possibility of mandating eIFU's to be made available via an existing TGA database. While Medicines Australia does not have any concerns with a possible mandate, as this is currently a requirement for prescription medicines, we suggest that other medical device sponsors are consulted to understand any concerns they may have and support be provided for any transition in the future.

Consultation question 8. Do you agree with the mentioned above requirements for supply of eIFU that manufacturers must meet? Why or why not?

For an integrated medicine/device, a separate risk assessment for eCMI/PI is not currently required and this should remain unchanged. Hence, we do not agree with requiring sponsors to undertake a risk analysis for every type of medical device. Instead, we suggest a risk-based approach where a risk assessment may be relevant for complex devices. It may be useful for the TGA to develop, in consultation with relevant stakeholders, guidance on categories of the various level of risk assessment required (this should also include a no-risk assessment group to ensure consistency with the approach for medicines).

We have no particular comments on the other possible requirements listed in the consultation document at this stage.

Consultation question 9. Are there any additional requirements for supply of eIFU that manufacturers must meet? Please explain.

While we do not have any suggested additional requirements for manufacturers to meet for supply of eIFU, we would like to suggest that the TGA approaches any reforms to IFU in a wholistic manner by ensuring that there are policy, process and systems alignment across all parts of the regulatory system (eg including PI and CMI for prescription medicines) as appropriate. For example, Medicines Australia has been advocating for TGO91 to be amended to allow digital instructions for use for the preparation of injectable medicines administered by health care professionals. The TGA is currently undertaking public consultation on this and other safety issues under TGO91. We therefore trust that the relevant sections of the TGA are in close communication to ensure that consistency in regulatory policy and processes is achieved to enhance the value and impact of digital information for patients and professionals across all therapeutic goods.

Thank you for the opportunity to provide feedback on the TGA consultation on availability of instructions for use in more flexible formats. To discuss any information in relation to this submission, please contact Ms Tham Vo, Senior Manager, Policy on tham.vo@medicinesaustralia.com.au.

Yours sincerely

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