THE AUSTRALASIAN COLLEGE OF DERMATOLOGISTS

**Media Statement** **6 March 2024**

# New Consensus Statement on Labelling of Dermatology AI-based Software

*The Australasian College of Dermatologists (ACD) have published a consensus statement on the minimum labelling requirements for dermatology artificial intelligence (AI)-based software as medical device (SaMD)*

Artificial intelligence (AI) holds remarkable potential to improve delivery of healthcare in Australia. However, like medicines and other health technologies, there are risks as well as benefits. "To ensure AI-based software can be used safely and effectively, end users such as health professionals and the general public need relevant and transparent information about the software," says ACD President, Dr Adriene Lee.

In dermatology, AI-based software can be found in mobile applications or integrated with skin imaging systems. While the Therapeutic Goods Administration (TGA) has established labelling requirements applicable to all medical devices, including Software as a Medical Device (SaMD), to date there are no separate specifications which highlight medical device labelling requirements in the context of dermatology AI software.

ACD's consensus statement, issued in February 2024 provides expert consensus and guidance for the TGA to set labelling standards about how the AI was developed and tested to safeguard patients. We hope these recommendations will be helpful for health professionals, consumers, industry and regulatory bodies, and welcome our ongoing collaboration with the TGA to support safe and appropriate regulation in this area of rapid innovation.

"AI in dermatology is still largely in research phase, and there is substantial evidence on the vulnerabilities of AI, particularly when it is used in patients or contexts that differ from the dataset that the AI has been trained in," says ACD Digital Health Committee member and lead author of the paper, Prof Victoria Mar. "In dermatology, this includes differences in skin colour, sex and age distribution, in image quality, and in the algorithm design."

In dermatology, only a few AI-based software have been approved by the major regulatory bodies such as the US FDA, UK's MHRA, European Notified Bodies or Australia's TGA. However, since capturing an image of your skin can be as easy as taking a photo on a smartphone, many of the available AI-based dermatology software products are general public-facing, such as smartphone apps, and have eluded such regulatory scrutiny.

"The availability of smartphone apps to self-diagnose skin cancer, when the AI is not yet at the point where it is sufficiently accurate for clinical let alone direct-to-consumer use, and the lack of readily available information about their risks and limitations is concerning", says Prof Mar.

"So that we can use the AI appropriately and interpret the results correctly, it is critical that we can understand how the AI was developed and the data used to train and test it. Like any product we use, the operating manual or product information should clearly explain when and how to use it safely and appropriately." says Prof Mar.

**--ENDS--**

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**Further Information**

*Minimum labelling requirements for dermatology artificial intelligence-based Software as Medical Device (SaMD): A consensus statement* is available to view here:
https://onlinelibrary.wiley.com/doi/10.1111/ajd.14222

**About the Australasian College of Dermatologists (ACD):**

The Australasian College of Dermatologists (ACD) is Australia's accredited training body and peak professional and membership organisation for medical specialists in dermatology. We are the Australian authority in skin, hair and nail health, education, information and advocacy.

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