

# **Australian Government**

### **Department of Health and Aged Care**

Therapeutic Goods Administration

Advertising Approval: Abbott Australasia – Information system software, app program, home healthcare (ARTG 226953), Invasive interstitial-fluid glucose monitoring system (ARTG 233514), Self-care monitoring web-based application software (ARTG 363331)

**Therapeutic Goods Act 1989** 

#### Approval under section 42DF for use of restricted representations by Abbott Australasia

I, Rowena Love, as a delegate of the Secretary to the Department of Health and Aged Care, on receipt of an application from Abbott Australasia, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representations described in paragraph (**A**), for use in advertisements for the products identified in paragraph (**B**), subject to the conditions identified in paragraph (**C**).

# (A)

- a. Representations referring to "diabetes" in the context of the Applicant's trading name "Abbott Diabetes Care"
- b. "[FreeStyle Libre 2] this product is indicated for measuring interstitial fluid glucose levels in people (aged 4 and older) with diabetes"
- c. "[FreeStyle Libre 2 Plus] this product is indicated for measuring interstitial fluid glucose levels in people (aged 2 and older) with diabetes
- d. "for people living with diabetes"
  - this representation will only be used in advertisements that include the representation 3.b. or 3.c. as applicable
- e. "subsidised for Australians with type 1 diabetes" with the statement 'eligibility criteria applies' displayed adjacent to the restricted representation and with the same prominence.

(together, the Representations)

### (B)

- Information system software, application program, home healthcare (ARTG 226953)
- Invasive interstitial-fluid glucose monitoring system (ARTG 233514)
- Self-care monitoring web-based application software (ARTG 363331)

(C)

Advertisements in which any one of the Representations is used must comply with the Therapeutic Goods Advertising Code.

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Dated this 28th day of April 25

Signed electronically

Rowena Love

Delegate of the Secretary to the Department of Health and Aged Care

Advertising and Compliance Education and Policy Section

Regulatory Compliance Branch