Therapeutic Goods (Prohibited Representations—HIV Pre-Exposure Prophylaxis) Permission 2020

I, Nicole McLay, as delegate of the Secretary of the Department of Health, make the following permission.

Dated 9 December 2020

Nicole McLay
Assistant Secretary
Regulatory Compliance Branch
Health Products Regulation Group
Department of Health

Contents

1 Name

This instrument is the *Therapeutic Goods (Prohibited Representations—HIV Pre-Exposure Prophylaxis) Permission 2020*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	The day after this instrument is made.	10 December 2020

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 42DK of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in section 3 of the Act, including the following:
(a) advertise;
(b) indication;
(c) label;
(d) medicine;
(e) Register; and
(f) therapeutic goods.

In this instrument:

Act means *Therapeutic Goods Act 1989*.

active ingredient has the same meaning as in the *Therapeutic Goods Regulations 1990*.

AFAO means the Australian Federation of AIDS Organisations Limited (ABN 91 708 310 631).

prohibited representation means a representation referred to in subsection 42DJ(1) of the Act.

registered medicine means a medicine included in the part of the Register for goods known as registered goods.

specified medicine means a registered medicine that:

(a) contains the active ingredients tenofovir and emtricitabine in combination, and no other active ingredients; and

(b) has an indication accepted in relation to its inclusion in the Register that relates to use of the medicine as pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired human immunodeficiency virus (HIV) in adults at high risk.

5 Permission

For subsection 42DK(3) of the Act, in relation to each item mentioned in the table in Schedule 1, the prohibited representations specified in column 2 are permitted to be used in the advertisements specified in column 3, about the therapeutic goods specified in column 4, subject to the conditions (if any) specified in column 5.

Schedule 1—Permission: prohibited representations

Note: See section 5.

Permitted use of prohibited representations				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Restricted representation**	**Advertisement**	**Therapeutic goods**	**Conditions**
1	a representation regarding the use of the therapeutic goods as pre-exposure prophylaxis (PrEP) to prevent, or reduce the risk of, sexually acquired human immunodeficiency virus (HIV)	an advertisement about the therapeutic goods that is made by, or on behalf of, the AFAO or a member of the AFAO	specified medicines	