Therapeutic Goods (Prohibited and Restricted Representations—HIV Self Tests) Permission 2021

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

Dated 14 October 2021

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

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Therapeutic Goods (Prohibited and Restricted Representations—Atomo HIV Self Test) Permission (No. 2) 2019 *6*

1 Name

This instrument is the *Therapeutic Goods (Prohibited and Restricted Representations—HIV Self Tests) Permission 2021*.

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.	15 October 2021

Note: This table relates only to the provisions of this instrument as originally made.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 subsection 3(1) of the Act, including the following:

(a) advertise;
(b) included in the Register;
(c) label;
(d) medical device;
(e) Register;
(f) Therapeutic Goods Advertising Code.

In this instrument:

Act means *Therapeutic Goods Act 1989*.

Class 4 IVD medical device has the same meaning as in the Medical Devices Regulations.

instructions for use has the same meaning as in the Medical Devices Regulations.

IVD medical device has the same meaning as in the Medical Devices Regulations.

IVD medical device for self-testing has the same meaning as in the Medical Devices Regulations.

Medical Devices Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

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

prominently displayed or communicated has the same meaning as in the Therapeutic Goods Advertising Code.

restricted representation means a representation referred to in section 42DD of the Act.

serious form, in relation to a disease, condition, ailment or defect, has the same meaning as in the Therapeutic Goods Advertising Code.

specified goods means an IVD medical device for self-testing that:

(a) is included in the Register; and

(b) is classified as a Class 4 IVD medical device; and

(c) has an intended purpose certified under section 41FD of the Act, and accepted in relation to the inclusion of the goods in the Register, that relates to the detection of the human immunodeficiency virus (HIV).

5 Permission

(1) For subsection 42DK(1) of the Act, in relation to each item mentioned in the table in Schedule 1, the representations specified in column 2 (to the extent that those representations are restricted representations) 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.

(2) For subsection 42DK(3) of the Act, in relation to each item mentioned in the table in Schedule 1, the representations specified in column 2 (to the extent that those representations are prohibited representations) 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.

6 Repeals

Each instrument that is specified in Schedule 2 to this instrument is repealed as set out in the applicable items in that Schedule.

Schedule 1—Permission

Note: See section 5.

Permitted use of prohibited and restricted representations				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Representation**	**Advertisement**	**Therapeutic goods**	**Conditions**
1	a representation regarding the treatment, cure, prevention, diagnosis (including screening), monitoring of, or susceptibility to: (a) sexually transmitted diseases; or (b) human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS)	an advertisement about the therapeutic goods in any form or media, including but not limited to, an advertisement that is: (a) on the label of the therapeutic goods; or (b) on the package in which the therapeutic goods are contained; or (c) on any material included with the package in which the therapeutic goods are contained	specified goods	all of the following: (a) the advertisement must not be inconsistent with the intended purpose of the therapeutic goods accepted in relation to the inclusion of the goods in the Register, and any conditions of inclusion relating to the goods; and (b) an advertisement about the therapeutic goods that is not: (i) on the label of the therapeutic goods; or (ii) on the package in which the therapeutic goods are contained; or (iii) on any material included with the package in which the therapeutic goods are contained; must contain statements, which are prominently displayed or communicated, to the effect of the following: (iv) the test may not detect HIV

Permitted use of prohibited and restricted representations				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Representation**	**Advertisement**	**Therapeutic goods**	**Conditions**
				acquired in the last 3 months so consult a medical practitioner if exposure was possible during this time; and (v) the test is a screening test and a positive test result requires confirmatory laboratory testing on the request of a medical practitioner
2	one or both of the following: (a) a representation regarding the treatment, cure, prevention, diagnosis (including screening), monitoring of, or susceptibility to: (i) sexually transmitted diseases; or (ii) human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS); (b) a representation that refers expressly, or by implication to a serious form of a disease, condition, or ailment where the representation is necessary to provide information about the	an advertisement made in accordance with item 1 that includes information about the proper use of the therapeutic goods (including, but not limited to, instructional videos, fact sheets, diagrammatic reference guides or instructions for use documents)	specified goods	

Permitted use of prohibited and restricted representations				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Representation**	**Advertisement**	**Therapeutic goods**	**Conditions**
	proper use of the therapeutic goods			

Note: The advertisements mentioned in the table must comply with the Act and the Therapeutic Goods Advertising Code, including requirements relating to the accuracy of the advertisements.

Schedule 2—Repeals

Note: See section 6.

Therapeutic Goods (Prohibited and Restricted Representations—Atomo HIV Self Test) Permission (No. 2) 2019

1 The whole of the instrument

Repeal the instrument.