

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

I, Nicole McLay, as delegate of the Secretary of the Depart of the hake the following permission.

Dated 10 April 2019

Nicole McLay
Assistant Secretary
Regulatory Education and mpliance buch
Health Products Regulation oup
Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Prohibited and Restricted Representations—Atomo HIV Self Test) Permission (No. 2) 2019.*

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 the table. Any other statement in column 2 has effect according to *i* terms.

Commencement info			
Column 1	Column 2	Col	13
Provisions	Commencement	<u>Da</u>	Detai ¹
1. The whole of this instrument	The day after this instrument is made.		

Note: This table relates only to the provisions of the instrume. originally made. It will not be amended to deal with any later a control of this country.

(2) Any information in column 3 of the pole is r, p of this instrument. Information may be inserted in this column part information in the pole is r, p of this instrument. Information may be inserted in this column part information in the pole is r, p of this instrument.

3 Authority

This instrument is made und tion 42 \(\) of the *Therapeutic Goods Act 1989*.

4 Definitions

Note:

A nu of expression used in this instrument are defined in section 3 of the Act, including the following the follow

- device where
- (b) cludea e Register;
- labe
- d) me al device,
- (e) Re ter; and
 - erapeutic Goods Advertising Code.

In this instrument:

Act means Therapeutic Goods Act 1989.

Atomo HIV Self Test means the Class 4 IVD medical device, Atomo HIV self test – HIV1/HIV2 antibody IVD, kit, immunochromatographic test (ICT), rapid (device number 311989), included in the Register with the commencement date 28 November 2018.

care card, in relation to the Atomo HIV Self Test, means the document in Schedule 6 to this instrument.

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

fact sheet, in relation to the Atomo HIV Self Test, means the document in Schedule 3 to this instrument.

instructions for use, in relation to the Atomo HIV Self Test, means the document in Schedule 4 to this instrument.

instructional video, in relation to the Atomo HIV Self Test, means the on-line instructional video referenced in the specific conditions in the entry on Register for the Atomo HIV Self Test.

label, in relation to the Atomo HIV Self Test, means the document, or 1 of the document, in Schedule 5 to this instrument.

prohibited representation has the same meaning as in sulection $\mathcal{D}J(1)$ of the Act.

restricted representation has the same meaning as needs of the Act.

Regulations means the *Therapeutic Goods* al Dev. Regulations 2002.

serious form, in relation to a disease, c dition in or derect, has the same meaning as in subsection 28(1) of the T rape of Go Advertising Code.

website means the website at ' mohin 't.co'

5 Permission—prohibited representation

For subsections 42 PV(2) and of the t, in relation to each item, the prohibited representation. Second column 2 of the table in Schedule 1 to this instrument are semitted to used:

- (a) on the late or
- (b) or nackae or
- (c) on other ateria muded with the package; or
- (d in the aver remen.

specified in column 3 of the lable, in relation to the therapeutic goods specified in column 4 of leather, subject to the conditions (if any) specified in column 5 of the table, anat Schedule.

57 aussica stricted representation

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

7 Repeals

Each instrument that is specified in Schedule 7 to this instrument is repealed as set out in the applicable items in that Schedule.

Schedule 1—Permission: prohibited representation

Note: See section 5.

Permitted use of prohibited representation						
Column 1	Column 2	Column 3	Column 4	Column 5		
Item	Prohibited representation	Advertisement	Therapeutic goods	Condition		
1	a representation regarding the treatment, cure, prevention, diagnosis (including screening), monitoring or susceptibility of, or pre-disposition to: (a) sexually transmitted diseases; and (b) human	fact sheet	Atomo HIV Self Test			
	immunodeficiency virus and acquired immune deficiency syndrome (HIV AIDS)					
2	a representation regarding the treatment, cure, prevention, diagnosis (including screening), monitoring or susceptibility of, or pre-disposition (a) sexually transitted diseases; and tited diseases; and tired nmune deficien. Is and tired nmune deficiency market (HI AIDS)	each of the following (instructors for significant contents) care contents	Atomo IV	the advertisements specified in column 3 must only be: (a) published or disseminated by means of the website; or (b) distributed with the goods specified in column 4		
?	a rep. Itation re rding the treat prevention, diagnosis (including screening), more algor susceptibility of, or pre-disposition to: (a) sexually transmitted diseases; and (b) human immunodeficiency virus and acquired immune deficiency syndrome (HIV AIDS)	each of the following: (a) instructional video; (b) other online content	Atomo HIV Self Test	the advertisement specified in column 3 must only be published or disseminated by means of the website		

Schedule 2—Permission: restricted representation

Note: See section 6.

Column 1	Column 2	Column 3	Column 4	Column 5
Item	Restricted representation	Advertisement	Therapeutic goods	Condition
1	a representation that refers to one or more serious forms of bleeding disorders, including haemophilia	instructions for use	Atomo HIV Self Test	the advertisement ecified in column 3 mus ally be: (a) published or discreted by the constant websita (b) stribut with he control pecified column 4

Schedule 3—Fact sheet

Note: See section 4, definition of fact sheet.



HIV SELF-TEST FACT SHEET

On 28 November 2018, an HIV self-test was approved for sale in Australia for the first time. The HIV self-test was made available for sale on 4 April 2019.



WHO SHOULD BE TESTING FOR HIV?

HIV testing is appropriate for anyone who may have been exposed to HIV. HIV exposure can occur through sexual contact without the use of an effective HIV prevention strategy (such as treatment as prevention, PrEP or condoms), sharing of needles or exposure to bodily fluids such as blood. HIV cannot be transmitted through casual contact such as hugging, kissing, or other skin to skin contact.

People who should consider routine, regular HIV testing include:

- gay and bisexual men and other men who have sex with men
- trans and gender diverse people
- · people who inject drugs
- people who have multiple partners or recent partner change
- sexual and injecting partners of people living with HIV
- people who are from have travelled to, or have partners from prevalence countries.

For gay and bisexual men, it is recommended to get tested to four times per year.



WHAT IS AN HIV SELF-TEST?

An HIV self-test is an HIV test that you ca rform yourself privacy of your own home or where eel comfortable. 1. HIV self-test available in Australia is disaccurate and easy t use. After you have completed the test, $y_{\rm c}$ be able to read result in fifteen minutes.

The HIV self-test is a cartridge. ... sirip. It is ining a p similar in size and et a USB (notuded in the self-test pack will be an HIV) test carry a set instruction, the of test fluid (which is indicated in the ablook in pile), a disputing a contacts in carry and all the self-test fluid (which is indicated in carry). about the te. Tur result.

rrently only one L a for sale in Australia, the V Self-Test. It is important to only buy devices approved for on he sure the result is accurate and that the device is



HOW DOES IT WORK?

st is a finger-prick blood test. The result is provided within inutes after performing the test.



HOW ACCURATE IS THE TEST?

The HIV self-test has been shown in laboratory testing to cor identify 99.6% of HIV negative and HIV positive samples.

Like other HIV tests, the self-test may not detect HIV that is recently acquired. For the HIV self-test, the wir months. This means that the test may not ____ HIV to ___ acquired in the last three months.

If you think you have exposed to hear ee more it is important to speak exposed to hear each clinic the potential exposure occompany within the exposure occording to the exposed to hear be eligible for post exposure p laxis (PE) HIV acquisition occurring



HOV JCH

The HIV's st will retain his shipping and handling.



WHERE D GET ON

tests are a ble for poase online at the following ou will be required to watch an al video on the proper use of the test prior to completing

V self-tests also be distributed or sold by organisations such as AIDS Cov. You can find a list of relevant local organisations to V self-tests ng a HIV self-test here.



WHAT HAPPENS IF I GET A POSITIVE RESULT?

While the self-test is very accurate, it is still a screening test. Because it is a screening test, getting a positive result does not necessarily mean you have HIV. If you have received a positive result on the selftest, it will still need to be confirmed with further testing by a doctor. You can refer to the enclosed Care Card for more information about accessing follow-up testing.

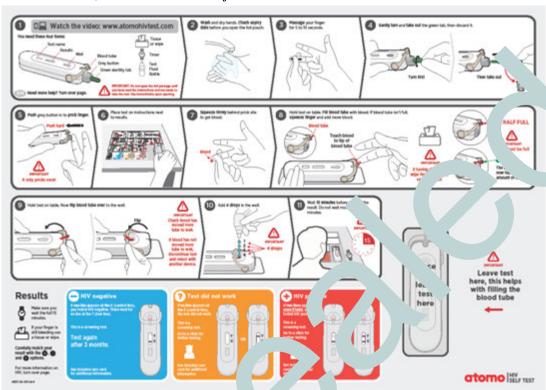
If you receive a positive result with the follow-up testing, it is important that you speak to a doctor about starting treatment. HIV is a manageable condition, treatment today is very effective and those living with HIV are able to live long and healthy lives

For more information on HIV self-testing please contact AFAO on (02) 9557 9399

LAST UPDATED: 2 APRIL 2019

Schedule 4—Instructions for use

Note: See section 4, definition of *instructions for use*.





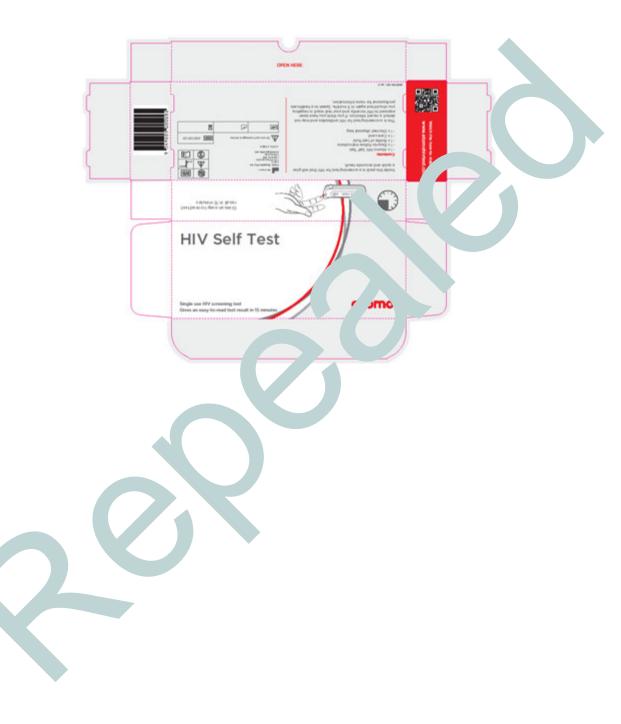
four Result

About HIV



Schedule 5—Label

Note: See section 4, definition of *label*.



Schedule 6—Care card

Note: See section 4, definition of care card.





REFERRAL REQUEST

Dear Healthcare Practioner,

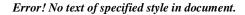
HIV SELF TEST USER REQUIRING FURTHER

The Atomo HIV Self Test gave a positive or inconclusive result for HIV (182) antibodies.

The test was performed on ___/ ___/ 20___

A follow-up confirmatory blood test for HIV is requested.





Schedule 7—Repeals

Note: See section 7.

Therapeutic Goods (Prohibited and Restricted Representations—Atomo HIV Self Test) Permission 2019

1 The whole of the instrument

Repeal the instrument.

