Therapeutic Goods (Prohibited and Restricted Representations—Chlamydia and Gonorrhoea Self Tests) Permission 2024

I, Sophie Boyson, as delegate of the Secretary of the Department of Health and Aged Care, make the following permission.

Dated 24 December 2024

Sophie Boyson
Acting Assistant Secretary
Regulatory Compliance Branch
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name

This instrument is the *Therapeutic Goods (Prohibited and Restricted Representations—Chlamydia and Gonorrhoea Self Tests) Permission 2024*.

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.	

Note: This table relates only to the provisions of this instrument as originally made.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 practitioner;
(e) Register;
(f) Therapeutic Goods Advertising Code.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

Class 3 IVD medical device has the same meaning as in the MD Regulations.

instructions for use has the same meaning as in the MD Regulations.

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

MD 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 3 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 bacterium Chlamydia trachomatis or the bacterium Neisseria gonorrhoea (or both).

5 Permission

(1) For subsection 42DK(1) of the Act, in relation to each item 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 specified goods, subject to the conditions (if any) specified in column 4.

(2) For subsection 42DK(3) of the Act, in relation to each item 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 specified goods, subject to the conditions (if any) specified in column 4.

Schedule 1—Permission

Note: See section 5.

Permitted use of prohibited and restricted representations			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Representation**	**Advertisement**	**Conditions**
1	a representation regarding the diagnosis (including screening) of chlamydia or gonorrhoea (or both)	an advertisement about the specified goods, including (but not limited to) an advertisement that is: (a) on the label of the goods; or (b) on the package in which the goods are contained; or (c) on any material included with the package in which the goods are contained	all of the following: (a) the advertisement must not be inconsistent with the intended purpose of the specified goods that is accepted in relation to the inclusion of the goods in the Register; (b) the advertisement must not be inconsistent with any conditions relating to the inclusion of the specified goods in the Register; (c) if the advertisement is not of a kind mentioned in paragraph (a) or (b) in column 3—the advertisement must contain statements, which are prominently displayed or communicated, to the effect of the following: (i) patients who are, or may be, pregnant should consult a medical practitioner before using the specified goods; (ii) the specified goods are only for testing vaginal swab samples; (iii) the specified goods are a screening test, and a positive test result requires confirmatory laboratory testing at the request of a medical practitioner; (iv) a negative test result may not be conclusive, and

Permitted use of prohibited and restricted representations			
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Item	**Representation**	**Advertisement**	**Conditions**
			patients are recommended to consult a medical practitioner; (v) the specified goods may not detect the bacterium Chlamydia trachomatis acquired in the last 60 days, and patients are recommended to consult a medical practitioner if exposure may have occurred during this time; (vi) the specified goods may not detect the bacterium Neisseria gonorrhoea acquired in the last 10 days, and patients are recommended to consult a medical practitioner if exposure may have occurred during this time; (d) the advertisement must not: (i) infer or make any statement to the effect that confirmatory testing is not required; or (ii) make any statement or claim relating to the accuracy, specificity, sensitivity or limit of detection of the specified goods, except where such statements or claims are included in the instructions for use; or (iii) include testimonials or endorsements

Permitted use of prohibited and restricted representations			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Representation**	**Advertisement**	**Conditions**
2	a representation that is necessary to provide information about the proper use of the specified goods, and is: (a) a representation regarding the diagnosis (including screening) of chlamydia or gonorrhoea (or both); or (b) a representation that refers expressly, or by implication, to a serious form of a disease, condition, ailment or defect	an advertisement about the specified goods made in accordance with item 1 that includes information about the proper use of the specified goods, including (but not limited to) the following: (a) instructional videos; (b) fact sheets; (c) diagrammatic reference guides; (d) instructions for use	