MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Standards for contraceptive devices in New Zealand

March 2024

Consultation outcome

Contents

About the consultation

Condoms and other contraceptive devices supplied in New Zealand are required to meet a gazetted standard. Section 6 of the Contraception, Sterilisation and Abortion Act 1977 grants the Minister of Health the power to approve standards for condoms or other contraceptive devices by notice in the New Zealand Gazette.

Updates to these standards were last notified in gazette notices dated 29 March 2014. Since that time, four of the five ISO standards gazetted at that time have been updated, one of the New Zealand standards that was gazetted has been removed and the second NZ standard is proposed for removal by Standards New Zealand standards that was gazetted has been removed and the second NZ standard is proposed for removal by Standards New Zealand.

Alignment of the NZ standard requirements with those accepted by other major international regulators ensures that contraceptive devices sold in New Zealand meet the current internationally accepted requirements. Alignment also removes any New Zealand-specific requirements that would hinder supply of devices into the market.

This consultation proposed replacing some older standards with the latest versions of these standards – as shown in Table 1.

Table 1: Contraceptive device standards under consultation

Standard to be replaced	Standard name	New standard
ISO 4074:2002e / Corrigenda 1:2003	Natural Latex Rubber Condoms, Requirements and test methods	ISO 4074:2015
ISO 25841:2011	Female Condoms – Requirements and test methods	ISO 25841:2017
ISO 8009:2004	Mechanical contraceptives – Reusable natural and silicone rubber contraceptive diaphragms, requirements and tests	ISO 8009:2014
ISO 7439:2011	Copper-bearing contraceptive intrauterine devices – Requirements and tests	ISO 7439:2015

The New Zealand Standard, NZS 7102:1980 *Specifications for Intra-Uterine Contraceptive Devices*, was withdrawn by Standards New Zealand in 2014. The consultation also sought confirmation that no contraceptive devices are currently being supplied that meet this withdrawn standard.

The consultation opened on 17 March 2020 and closed on 14 May 2020. The consultation was published on the Medsafe website. Known suppliers, industry organisations and others known to have an interest in these standards were contacted and informed of the consultation.

Submissions received

Thank you to everyone who responded to the consultation

We have analysed and summarised the consultation results.

The results have been divided into four parts:

1. Overview of respondents
2. Consultation feedback
3. Outcome
4. Implementation

Part one summarises the respondent demographics by individual or organisation, location, respondent category, and by health profession (if applicable).

Part two contains a tabulated summary of respondents' agreement or disagreement with the proposed update to the contraceptive device standards included in this consultation.

Part three is the consultation outcome and part four the implementation date.

Part One: Overview of Respondents

Medsafe received 11 submissions.

- Five were from individuals and six were on behalf of an organisation or group (see Table 1).
- Respondents included importers, health care professionals, members of the public, manufacturers, sponsors (suppliers), industry organisations, and a community health organisation (Table 2).
- Most respondents were based in New Zealand (Table 3).

Table 1: Respondent type – individual or organisation

Response	Number	Percentage (%)
As an individual	5	45
On behalf of an organisation or group	6	55
Not Answered	0	0
Total	**11**	**100**

Table 2: Respondent role

Response	Number	Percentage (%)
Health care professional[a]	3	27
Member of the public	2	18
Sponsor	1	9
Manufacturer	1	9
Importer	1	9
Industry organisation	1	9
Other[b]	2	18
Total	**11**	**100**

Notes

a. The three respondents identifying as health care professionals were a pharmacist, a midwife and a sexual health nurse.

b. One of the two respondents that identified as 'other' identified as a civilian and the other identified as representing a community health organisation.

Table 3: Respondent location

Response	Number	Percentage (%)
New Zealand	8	73
Other	2	18
Not Answered	1	9
Total	**11**	**100**

Part Two: Consultation Feedback

1: Do you have any objection to replacing ISO 4074:2002e/Corrigenda 1:2003 Natural Latex Rubber Condoms, Requirements and Test Methods with ISO 4074:2015?

Response	Number	Percentage (%)
No, I have no objection	9	82
Yes, and I will describe this below	1	9
Not Answered	1	9
Total	**11**	**100**

Comments: natural latex rubber condoms

- Four respondents added comments in support of the proposed change.
- One did not respond and provided no reason for this.
- One did not support the change on the basis that they did not have enough information about the change.

2: Do you have any objection to replacing ISO 25841:2011 Female Condoms – Requirements and Test Methods with ISO 25841:2017?

Response	Number	Percentage (%)
No, I have no objection	9	82
Yes, and I will describe this below	1	9
Not Answered	1	9
Total	**11**	**100**

Comments: female condoms

Four respondents provided comments.

- One respondent said this product was not relevant to them.
- One supported any change to align with international standards.
- One did not market this product but supported the change.
- One did not have enough information about the change.

3: Do you have any objection to replacing ISO 8009:2004 Mechanical Contraceptives – Reusable natural and silicone rubber contraceptive diaphragms, requirements and tests with ISO 8009:2014?

Response	Number	Percentage (%)
No, I have no objection	7	64
Yes, and I will describe this below	3	27
Not Answered	1	9
Total	**11**	**100**

Comments: mechanical contraceptives

Six respondents commented on the proposed change.

- For the three respondents that did not object, either the product was not relevant, not marketed, or they supported alignment with international standards.
- The reasons provided for objecting to the change by three respondents were lack of knowledge of the change, the product was no longer available, and for one respondent the proposed standard still did not permit sale in New Zealand of a product developed by the company.

4: Do you have any objection to replacing ISO 7439:2011 Copper-bearing contraceptive intrauterine devices – Requirements and Tests with ISO 7439:2015?

Response	Number	Percentage (%)
No, I have no objection	8	73
Yes, and I will describe this below	1	9
Not Answered	2	18
Total	**11**	**100**

Comments: copper IUDs

There were four comments relating to this question.

- One respondent did not market the product but supported the change.
- One respondent did not support the change as they did not understand what was involved in the change.
- One respondent noted that they provide copper-bearing IUDs but that they are not responsible for assessing standards.
- One respondent noted that the proposed change was not relevant to them.

5: Do you currently market products that comply with NZS 7102:1980 – Specifications for Intra-Uterine Contraceptive Devices?

Response	Number	Percentage (%)
Yes	0	0
No	8	73
Not Answered	3	27
Total	**11**	**100**

6: Do you currently market intra-uterine contraceptive devices that are not copper bearing?

Response	Number	Percentage (%)
Yes	0	0
No	10	91
Not Answered	1	9
Total	**11**	**100**

Comments: non-copper bearing IUCDs

- There was 1 comment provided advising that this was not applicable.

7: Do you currently market polyurethane condoms?

Response	Number	Percentage (%)
Yes	1	9.
No	9	82
Not Answered	1	9
Total	**11**	**100**

Comments: polyurethane condoms

- There was 1 comment from a provider who advised it was assumed all funded product met the standard.

8: Do you have any objection to replacing NZS 7106:1998 – Polyurethane Condoms with ISO 23409:2011 Male Condoms – Requirements and test methods for condoms made from synthetic materials?

Response	Number	Percentage (%)
No, I have no objection	9	82
Yes, and I will describe this below	1	9
Not Answered	1	9
Total	**11**	**100**

Comments: male condoms

Five respondents commented on this question.

- The respondent that did not answer commented that they supported any change to international standards.
- The respondent that did not support the change commented that they did not understand the proposed change.
- Of the three respondents that identified no objection, two commented positively on the change and one identified that this product was not relevant to them.

9: Do you have any other comments?

There were five responses to this question.

- One respondent commented 'no'.
- Two respondents identified difficulty with not for profit organisations accessing the standards as there was a cost involved.
- One respondent commented positively on the proposed changes.

- One respondent asked whether Medsafe will be implementing any processes to ensure that sponsors are complying with gazetted standards.

Other

When reviewing the consultation feedback, Medsafe identified that one sole supplier of one of the product types in the consultation had not participated. This supplier was contacted and confirmed no objection to the proposed changes for the product currently supplied.

Part Three: Outcome

After consideration of the consultation feedback, Medsafe has decided that the updated standards should be recommended for gazettal.

Medsafe will arrange for the four new standards to be gazetted.

Part Four: Implementation

The new standards will be effective from the date of the gazette notice. Any new product imported or introduced to the market must comply with the new standard.