6.03 MIFEPRISTONE AND MISOPROSTOL, Pack containing 1 tablet mifepristone 200 mg and 4 tablets misoprostol 200 micrograms, MS-2 Step®, MS Health Pty Ltd.

1 Purpose of submission

1.1 The Category 2 submission requested a change to the existing General Schedule, Authority Required (STREAMLINED) listing of mifepristone and misoprostol (MS-2 Step®) for the termination of an intra-uterine pregnancy, such that the condition must be an intra-uterine pregnancy of up to 70 days of gestation (compared to 63 days of gestation with the existing listing).

1.2 The listing was requested on the basis of a cost comparison of medical termination of pregnancy (MTOP) using MS-2 Step versus surgical termination of pregnancy (STOP).

Table 1: Key components of the clinical issue addressed by the submission (as stated in the submission)

Component	Description
Population	Women of childbearing age seeking termination of an intra-uterine pregnancy of up to 70 days of gestation.
Intervention	Medical termination of pregnancy (MTOP) comprised of: Mifepristone 200 mg, one tablet, taken orally. Followed 36 to 48 hours later by 800 mcg misoprostol, administered buccally. MS-2 Step is provided as a co-pack.
Comparator	Surgical termination of pregnancy (STOP) comprised of manual or electrical vacuum aspiration +/- cervical priming with 400 mcg misoprostol administered vaginally or buccally 1-3 hours prior to surgery.
Outcomes	Rate of successfully completed abortion. Frequency of repeat procedures for incomplete abortion. Unplanned hospital admissions. Number of continued pregnancies. Side effects and/or adverse events. Infections. Infections requiring antibiotics. Pain. Uterine puncture, cervical tears. Bleeding. Haemorrhage. Blood transfusions.
Clinical claim	In women of child-bearing age seeking termination of an intra-uterine pregnancy of up to 70 days gestation, mifepristone 200 mg orally followed 36-48 hours later by misoprostol 800 mcg buccally is as effective as surgical termination of pregnancy in terms of successful complete abortion. Both medical and surgical abortions are safe and acceptable to women. The safety and tolerability of the methods are different and not directly comparable.

Source: Table 1.1, p16 of the submission.
Italics corrected during evaluation.

2 Background

Registration status

2.1 Mifepristone and misoprostol were first registered on the Australian Register of Therapeutic Goods (ARTG) on 29 August 2012 for pregnancy termination up to 49 days' gestation. The MS-2 Step, a composite pack containing one tablet mifepristone 200 mg and four tablets misoprostol 200 mcg, was subsequently registered on 4 June

2014, with the indication extended to termination of pregnancy up to 63 days' gestation.

2.2 In September 2025, the Therapeutic Goods Administration (TGA) accepted an application to extend the gestational age limit to 70 days. The Delegate's Overview (received 2 July 2026) was supportive of increasing the current indication for the medical termination of an intrauterine pregnancy from 63 to 70 days of gestation.

2.3 Additionally, the TGA is evaluating a new indication for MS-2 Step for "the medical management of miscarriage up to 70 days of gestation, determined by ultrasound equivalence rather than last menstrual period"; however, this was not proposed in the current PBAC submission.

2.4 On 3 February 2026, Arzestra® containing mifepristone 200 mg and misoprostol 200 microgram tablets was also listed on the ARTG for medical termination of an intra-uterine pregnancy, up to 63 days of gestation. This brand has now been PBS listed for this indication alongside with MS-2 Step.

Previous PBAC consideration

2.5 At its March 2013 meeting, the PBAC recommended the listing of the separate components, mifepristone 200 mg (Mifepristone Linepharma®) and misoprostol 200 microgram (GyMiso 200®), for termination of an intra-uterine pregnancy up to 49 days' gestation on the basis of non-inferior effectiveness and lower cost versus STOP.

2.6 At its July 2014 meeting, the PBAC recommended the listing of MS-2 Step for the termination of an intra-uterine pregnancy of up to 63 days' gestation on the basis of non-inferior effectiveness against STOP, in line with the revised TGA indication. The restriction level of MS-2 Step was changed from Authority Required to Authority Required (STREAMLINED) on 1 August 2023.

For more detail on PBAC's view, see section 7 PBAC outcome.

3 Requested listing

MEDICINAL PRODUCT medicinal product pack	Dispensed Price for Max. Qty	Max. qty packs	Max. qty units	№.of Rpts	Available brands
MIFEPRISTONE (&) MISOPROSTOL					
mifepristone 200 mg tablet [1] (&) misoprostol 200 microgram tablet [4], 1 pack	$391.06	1	1	0	MS-2 Step
Category / Program: General Schedule					
Prescriber type: ☒Medical Practitioners ☒Midwife ☒Nurse practitioners					
Restriction type: ☒Authority Required (STREAMLINED)					
Indication: Termination of an intra-uterine pregnancy					
Clinical criteria:					
The condition must be an intra-uterine pregnancy of up to 70 days of gestation					
Administrative Advice: Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised.					

3.1 The requested dispensed price for maximum quantity (DPMQ) for MS-2 Step remained unchanged at $391.06. Although the PSCR and pre-PBAC response requested that, given the imminent arrival of a generic and the viability issues for MS-2 Step due to loss of market share and ongoing price disclosure, the appropriateness of a price increase to ensure sustainability of the listing be considered, the PBAC noted that no formal submission requesting a higher price was presented.

3.2 The requested listing was consistent with the current PBS listing of MS-2 Step. The only change is the extension of the gestational age limit from 63 days to 70 days.

For more detail on PBAC's view, see section 7 PBAC outcome.

4 Population and disease

4.1 While both surgical and medical abortion methods are legalised for termination of pregnancies (TOP) in Australia, access remains suboptimal and the financial burden persists among the vulnerable cohort of women. Accessibility and cost vary widely according to Medicare eligibility, the type of termination, type of provider, the gestational age of the pregnancy and geographical location[1].

4.2 The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) Clinical Guideline for abortion care (2025) [2] states that women should be

[1] Commonwealth of Australia, (2023), 'The Senate Community Affairs Reference Committee: ending the postcode lottery: Addressing barriers to sexual, maternity and reproductive healthcare in Australia'. https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/ReproductiveHealthcare/Report

[2] Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), 2025, 'Clinical

offered a choice of abortion method, free from coercion, based on adequate information and alignment with their values and preferences. Choice of method depends on individual preference, service availability, and evidence regarding each method, and may be influenced by prior experience, pregnancy loss, or childbirth[2].

4.3 For medical abortion up to 10 weeks' gestation, the RANZCOG Clinical Guideline recommends using mifepristone 200 mg orally, followed 24-48 hours later by misoprostol 800 mcg by buccal, sublingual or vaginal route.

4.4 Mifepristone is a synthetic steroid with an anti-progesterone action which antagonises the endometrial and myometrial effects of progesterone, sensitises the myometrium to the contraction inducing action of prostaglandins and allows dilatation of the uterine cervix. Misoprostol is a synthetic analogue of prostaglandin E1 which induces contraction of smooth muscle fibres in the myometrium and relaxation of the uterine cervix. When used in the recommended sequential regimen, MS-2 Step increases the success rate of TOP and accelerates the expulsion of the conceptus.

4.5 As stated in paragraph 2.6, MS-2 Step is currently PBS-listed for the medical termination of pregnancies with a gestational age up to 63 days. During the 2023 Senate Inquiry[1], several submissions proposed to increase the gestational age limit for termination, as the current nine-week (or 63 days) limit is not aligned with the RANZCOG Clinical Guideline or international best practice and that many countries allow the use of MS-2 Step up to 10 weeks' gestation (or 70 days). Consequently, the population targeted in this submission comprised women of child-bearing age seeking termination of an intra-uterine pregnancy of up to 70 days' gestation.

4.6 For surgical abortions, the RANZCOG Clinical Guideline recommends both manual vacuum aspiration and electric vacuum aspiration as suitable options up to 14 weeks' gestation[2]. Additionally, cervical priming with misoprostol is recommended to reduce the risk of incomplete abortion, ongoing pregnancy, future cervical insufficiency and preterm birth, and the need for mechanical dilatation[2].

For more detail on PBAC's view, see section 7 PBAC outcome.

5 Comparator

5.1 The submission nominated first-trimester STOP as the main comparator, on the basis that there is no approved or listed pharmaceutical analogue for MTOP. The ESC considered that the proposed comparator was appropriate and aligned with previous PBAC submissions for MS-2 Step (Mifepristone and misoprostol, Public Summary Document [PSD], March 2013 and July 2014 PBAC meetings) as well as with the RANZCOG Clinical Guideline.

For more detail on PBAC's view, see section 7 PBAC outcome.

Guideline for Abortion Care: An evidence-based guideline on abortion care in Australia and Aotearoa New Zealand'. Available at: https://ranzcog.edu.au/wp-content/uploads/Clinical-Guideline-Abortion-Care.pdf.

6 Consideration of the evidence

Sponsor hearing

6.1 There was no hearing for this item.

Consumer inputs

6.2 The PBAC noted and welcomed the input from individuals (1), health care professionals (39) and organisations (3) via the Office of Health Technology Assessment Consultation Hub. Although the input from the individual was not directly related to the requested indication, it reflected lived experiences with MS-2 STEP that could be considered relevant to the broader context of its use.

6.3 The input received from the health professionals was generally supportive of extending the PBS listing of MS-2 STEP. The main benefits identified were improved access to timely care, particularly for women in rural and remote areas and those facing delays due to ultrasound, appointments, travel, cost, or provider shortages. The health professionals noted that the current 63-day limit can force patients into more invasive, expensive, or less accessible surgical pathways, and extending the gestational limit would improve equity, privacy, patient choice, and the ability to receive care closer to home, including through telehealth. Benefits were also highlighted for priority populations, including Aboriginal and Torres Strait Islander women and other disadvantaged groups.

6.4 Health professionals also noted extending access could reduce pressure on hospital services; lower costs for patients and the health system. Several contributors stated the change would align PBS-listing with current clinical guidelines and existing evidence on safety and effectiveness up to 70 days.

6.5 Concerns raised by the health professionals included: a possible small reduction in efficacy at later gestations; slightly increased bleeding and pain; retained products of conception; and the need for stronger counselling, follow-up, and referral pathways. A small number of contributors expressed concern about increased risk beyond 63 days or about patients using the medicine outside the approved window.

6.6 The PBAC noted the advice received from the consumer groups, The Early Pregnancy Loss Coalition and Children by Choice, which highlighted the need for access to safe, timely and affordable pregnancy termination care. They noted that extending access to 70 days would help avoidable inequity in early termination care and would provide a small, but important, increase in time for people who face delays in diagnosis, referral, counselling, travel, ultrasound access or finding an available prescriber. It was stated that the change would particularly benefit people in regional and remote areas, young people, those experiencing domestic family violence or reproductive coercion who may need to conceal the abortion as a miscarriage or pregnancy loss and those experiencing financial hardship.

6.7 The PBAC noted the advice received from the Australian College of Midwives also

supported the expanded criteria for MS-2 STEP, stating that it was fundamental in the provision of safe, equitable and timely termination of pregnancy care.

Clinical trials

6.8 The submission was based on one randomised controlled/partially-randomised patient preference trial comparing MTOP using oral mifepristone 200 mg followed by vaginal misoprostol 800 mcg with STOP in women at 10–13 weeks' amenorrhoea, with a mean estimated gestation of 72.0 days (standard deviation [SD]: 7.0; Ashok et al. 2002). Subgroup analyses of women with gestational age between 64 and 70 days were relied upon to support the clinical claim.

6.9 Ashok et al. (2022) enrolled 445 women who were allocated to 4 groups: those randomised to MTOP (n = 188; 42.2%), those randomised to STOP (n = 180; 40.4%), those who had a strong preference for MTOP (n = 15; 3.4%) and those who had a strong preference for STOP (n = 62; 13.9%).

6.10 The submission noted that the route of misoprostol administration in Ashok et al. (2002) was vaginal, differing from the approved buccal administration in Australia. The submission argued this difference was unlikely to affect the overall study findings, noting that comparative studies of misoprostol administered via different routes of administration have previously been considered acceptable by the PBAC for the listing of MS-2 Step for use up to 49 and 63 days' gestation (Mifepristone and misoprostol, PSD, July 2014 PBAC meeting). This was consistent with the RANZCOG Clinical Guideline, which reports no difference between buccal and vaginal administration in rates of successful abortion, safety and satisfaction outcomes[2].

6.11 In Ashok et al. (2002), if the products of conception were not passed, a further two doses (400 mcg) of misoprostol were given either orally or vaginally at three hours intervals depending on vaginal bleeding. The median number of misoprostol doses reported was two; however, outcomes were not stratified by gestational age, and the impact of additional doses of misoprostol on the complete abortion/intrauterine evacuation rate in women with 64-70 days' gestation was uncertain. In Australian clinical practice, additional doses are not recommended for MTOP up to 70 days' gestation but form part of the recommended protocol beyond 10 weeks' gestation[2].

6.12 As the misoprostol component in Ashok et al. (2002) was administered vaginally and the trial protocol permitted additional doses of misoprostol if required, six supportive studies were presented to inform the applicability of the comparative efficacy between MTOP and STOP to the Australian treatment regimen. While these studies were broadly applicable with respect to dose and route of administration, some had limited applicability to the requested population, as outcomes were not stratified by gestational age (Boersma et al., 2011; Tan et al., 2018; Olavarrieta et al., 2015), or included less than 15% of women with gestational age 64-70 days (Sanhueza Smith et al., 2015; Boersma et al., 2011; Tan et al., 2018).

6.13 Details of the trials presented in the submission are provided in Table 2.

Table 2: Trials and associated studies presented in the submission

Trial ID	Protocol title/ Publication title	Publication citation
Direct trials MTOP vs. STOP in gestation up to 70 days		
Ashok et al., 2002	Ashok PW, Kidd A, Flett GM et al. A Randomised Comparison of Medical Abortion and Surgical Vacuum Aspiration at 10-13 Weeks Gestation.	*Hum Reprod.* 2002; 17(1):92-8
Supportive trials using MTOP in gestation up to 70 days		
Winikoff et al., 2012	Winikoff B, Dzuba IG, Chong E et al. Extending outpatient medical abortion services through 70 days of gestational age.	*Obstet Gynecol.* 2012; 120(5):1070-6
Sanhueza Smith et al., 2015	Sanhueza Smith P, Peña M, Dzuba IG et al. Safety, efficacy and acceptability of outpatient mifepristone-misoprostol medical abortion through 70 days since last menstrual period in public sector facilities in Mexico City.	*Reprod Health Matters.* 2015; 22(44 Suppl 1):75-82.
Dzuba et al., 2020	Dzuba IG, Chong E, Hannum C et al. A non-inferiority study of outpatient mifepristone-misoprostol medical abortion at 64-70 days and 71-77 days of gestation.	*Contraception.* 2020; 101(5):302-8.
Boersma et al., 2011	Boersma AA, Meyboom-de Jong B, Kleiverda G. Mifepristone followed by home administration of buccal misoprostol for medical abortion up to 70 days of amenorrhoea in a general practice in Curaçao.	*Eur J Contracept Reprod Health Care*. 2011; 16(2):61-6.
Tan et al., 2018	Tan YL, Singh K, Tan KH et al. Acceptability and feasibility of outpatient medical abortion with mifepristone and misoprostol up to 70 days gestation in Singapore.	*Eur J Obstet Gynecol Reprod Biol.* 2018; 229:144-7.
Olavarrieta et al., 2015	Olavarrieta CD, Ganatra B, Sorhaindo A et al. Nurse versus physician-provision of early medical abortion in Mexico: a randomized controlled non-inferiority trial.	*Bull World Health Organ.* 2015; 93(4):249-58.

Source: Table 2.3, p31 of the submission.
MTOP = Medical termination of pregnancy; STOP = Surgical termination of pregnancy

6.14 The key features of the direct head-to-head trial and supporting evidence are summarised in Table 3.

Table 3: Key features of the included evidence

Trial	N	Patients with gestational age 64-70 days	Design	Risk of bias	Patient population	Outcome(s)
Direct trials MTOP vs. STOP						
Ashok et al., 2002	N = 486 MTOP: 217 STOP: 269	MTOP: 105 STOP: 108	R, PRPP	High[a]	Women seeking TOP at 64-91d gestation, confirmed by ultrasound	Primary: complete intrauterine evacuation Secondary: medical complications, adverse events, patient preferences and acceptability.
Supportive studies using MTOP						
Winikoff et al., 2012	N = 729 57-63d: 379 64-70d: 350	MTOP: 304	P, OL	High[a]	Women seeking TOP at 57-70d gestation, confirmed by ultrasound	Primary: complete abortion without surgical intervention, regardless of the number of misoprostol doses used. Secondary: side effects, patient satisfaction and acceptability, days of heavy bleeding, days of missed work or school, number of calls and unscheduled clinic visits.
Sanhueza Smith et al., 2015	N = 1,001	MTOP: 148	OL	High[a]	Women seeking TOP at ≤70d gestation	Primary: complete abortion without vacuum aspiration. Secondary: extent of bleeding, extend of pain, other side effects, rate of abortions needing further treatment, and acceptability.
Dzuba et al., 2020[b]	N = 719 64-70d: 393 71-77d: 326	MTOP: 388	P, OL, NI	High[a]	Women seeking TOP at 64-77d gestation, confirmed by ultrasound	Primary: abortion success. Secondary: side effects, days of heavy bleeding, time to expulsion, and participant satisfaction and acceptability.
Boersma et al., 2011[b]	N = 331	MTOP: 26	P	High[a]	Women seeking TOP at ≤70d gestation	Complete abortion and safety.
Tan et al., 2018[b]	N = 130	MTOP: 11	P, Pilot	High[a]	Women seeking TOP at ≤70d gestation	Primary: successful abortion. Secondary: women's preferences for the location of mifepristone administration and women's satisfaction.
Olavarrieta et al., 2015[b]	N = 1,017 Physician:514 Nurse: 503	Not specified	R, C, NI	High[a]	Women seeking TOP at ≤70d gestation	Primary: complete abortion without the need for surgical intervention. Secondary: women's satisfaction, and adverse events.

Source: Section 2.3.1.1, p34; Table 2.5, p35; Table 2.8, p39; Table 2.18, p54; Table 2.19, pp54-56 of the submission.
C = controlled; d = day; OL = open label; MTOP = Medical termination of pregnancy; N = total participants in group; NI = non inferiority; P = prospective; PRPP = partially-randomised patient preference, R = randomised; STOP = Surgical termination of pregnancy; TOP = termination of pregnancy.
[a] High risk of bias due to confounding from non-random allocation and no evidence of concealment in treatment allocation, testing and outcome assessment.
[b] These studies had limited applicability given <15% of the included population had gestation age of 64-70 days, or no stratification by gestational age.

Comparative effectiveness

6.15 The primary efficacy outcome in all studies was complete abortion/intrauterine evacuation. Secondary outcomes included medical complications, patient preferences

and acceptability, and adverse events. These clinical and patient-relevant outcomes for benefits and harms were consistent with the previous PBAC submission (Mifepristone and misoprostol, PSD, March 2013 PBAC meeting).

Complete abortion/Complete intrauterine evacuation

6.16 The efficacy of medical versus surgical abortions, stratified by gestational age, in Ashok et al. (2002) is presented in Table 4.

Table 4: Results of the efficacy of medical and surgical abortions (per protocol population; Ashok et al., 2002)

Gestation	MTOP, n (%) N=203	STOP, n (%) N=242	Risk difference (95% CI)
64-70 days			
Total number	105 (51.7)	108 (44.6)	-
Failed	3 (2.9)	0 (0)	2.9% (-0.3, 6.0)
Complete abortion	102 (97.1)	108 (100)	-2.9% (-6.0, 0.3)
71-77 days			
Total number	52 (25.6)	57 (23.6)	-
Failed	4 (7.7)	3[a] (5.3)	2.4% (-6.8, 11.7)
Complete abortion	48 (92.3)	54 (94.7)	-2.4% (-11.7, 6.8)
78-84 days			
Total number	32 (15.8)	63 (26.0)	-
Failed	4 (12.5)	2 (3.2)	9.3% (-2.9, 21.6)
Complete abortion	28 (87.5)	61 (96.8)	-9.3% (-21.6, 2.9)
85-91 days			
Total number	14 (6.9)	14 (5.8)	-
Failed	0 (0)	0 (0)	-
Complete abortion	14 (100)	14 (100)	NR
Overall			
Total number	203	242	-
Failed	11 (5.4)	5 (2.1)	3.4% (-0.2, 6.9)
Complete abortion	192 (94.6)	237 (97.9)	-3.4% (-6.9, 0.2)

Source: Table 2.21, p58 of the submission.

CI = confidence interval; MTOP = medical termination of pregnancy; n = number of participants reporting data; N = total participants in group; NR = not reported; STOP = surgical termination of pregnancy

[a] In one woman, medical treatment was undertaken following an attempt at surgery, due to an inability to dilate the cervix

6.17 For MTOP, Ashok et al. (2002) reported a 97.1% complete abortion/intrauterine evacuation rate among women at 64-70 days' gestation and a 94.6% success rate in the overall population.

6.18 The effectiveness of MTOP appeared to decline with increasing gestational age, decreasing from 97.1% at 64-70 days to 87.5% at 78-84 days' gestation, which was consistent with PBAC's earlier conclusion that the effectiveness of MTOP declines as gestational age increases (paragraph 7.3, Mifepristone and misoprostol, PSD, March 2014 PBAC meeting).

6.19 For STOP, Ashok et al. (2002) reported a 0% abortion failure among women at 64-70 days' gestation and a 2.1% failure rate in the overall population. The Royal College of Obstetricians and Gynaecologists (RCOG) stated that surgical abortion results in approximately one continuing pregnancy per 1,000 procedures, with slightly higher

rate in pregnancies of less than seven weeks[3], indicating a very low abortion failure rate.

6.20 Overall, MTOP was associated with no statistically significant difference in complete abortion/intrauterine evacuation compared with STOP among women with gestational ages between 64 and 91 days (94.6% vs. 97.9%, risk difference [RD] = -3.4%; 95% confidence interval [CI]: -6.9, 0.2).

6.21 In the subgroup of women with gestational age 64–70 days, which was the target population of this submission, similarly there was no statistically significant difference in complete abortion rates between MTOP and STOP (97.1% vs. 100%, RD = -2.9%; 95% CI: -6.0, 0.3). The submission did not propose a minimum clinically important difference (MCID) for complete abortion/intrauterine evacuation, and while limited literature[4,5] has applied a non-inferiority margin of approximately 5% for the risk difference between treatments. No formally established MCID exists for abortion methods.

6.22 These findings were consistent with those previously presented to the PBAC, which reported a difference in abortion failure of 1.6% (95% CI: -0.6, 3.8) among women with gestational age ≤49 days and 6.0% (95% CI: 2.5, 9.5) among women with gestational age >49 days (Table 5, Mifepristone and misoprostol, PSD, July 2014 PBAC meeting).

6.23 The efficacy of medical abortion using oral mifepristone and buccal misoprostol, which is the approved treatment regimen in Australia, from the supportive studies is summarised in Table 5.

Table 5: Summary of complete abortion/intrauterine evacuation rates of oral mifepristone and buccal misoprostol in the supportive studies

Study	Complete abortion/intrauterine evacuation rate
64-70 days gestation	
Winikoff et al., 2012	92.8%
Sanhueza Smith et al., 2015	91.2%
Dzuba et al., 2020	92.3%
Up to 70 days gestation	
Boersma et al., 2011	97.7%
Tan et al., 2018	96.8%
Olavarrieta et al., 2015	98.2%

Source: Table 2.26, p61 of the submission; Sanhueza Smith et al (2015).

6.24 Among women with 64-70 days' gestation, the complete abortion/intrauterine evacuation rate following MTOP was approximately 91-93%, based on three supportive studies (Winikoff et al., 2012; Sanhueza Smith et al., 2015; Dzuba et al., 2020). This was slightly lower than the 97.1% rate reported in Ashok et al. (2002).

[3] Royal College of Obstetricians and Gynaecologists (RCOG), (2022), 'Best practice in abortion care', RCOG, Available at: https://www.rcog.org.uk/media/geify5bx/abortion-care-best-practice-paper-april-2022.pdf

[4] Iyengar K., Paul M., Iyengar S.D. et al. (2015), 'Self-assessment of the outcome of early medical abortion versus clinic follow-up in India: a randomised, controlled, non-inferiority trial', Lancet Glob Health 3(9):e537-45.

[5] Kapp N., Mao B., Menzel J., et al. (2023), 'A prospective, comparative study of clinical outcomes following clinic-based versus self-use of medical abortion', BMJ Sex Reprod Health 49(4):300-307

6.25 In contrast, complete abortion/intrauterine evacuation rates of approximately 97-98% were reported in Boersma et al. (2011), Tan et al. (2018), and Olavarrieta et al. (2015). These high rates are likely attributable to the gestation age of women in these studies, as majority (≥85%) had a gestational age of ≤63 days. As noted previously by the PBAC, abortion success rates with MTOP tend to decline slightly with increasing gestational age, particularly into the second trimester (paragraph 7.3, Mifepristone and misoprostol, PSD, March 2014 PBAC meeting).

Medical sequelae

6.26 The medical sequalae in Ashok et al. (2002) were based on all included participants with a gestational age of ≥64 days, without stratification by gestational age. The medical sequelae at Week 2 to 3, and Week 8 following TOP are presented in Table 6 and Table 7, respectively.

Table 6: Medical sequelae at Week 2 to 3 following abortion in Ashok et al. (2002)

	Randomised			Preference		
	MTOP n=118	**STOP n=111**	**Mean change (CI)**	**MTOP n=9**	**STOP n=36**	**Mean change (CI)**
Total number of days bleeding, Mean (SD)	14.2 (4.8)	11.2 (5.9)	**3.0 (1.6, 4.4)**	13.0 (4.1)	10.8 (4.7)	2.2 (-1.5, 5.9)
Total vaginal bleeding score, Mean (SD)	37.6 (13.7)	23.3 (14.8)	**14.3 (10.6, 18.0)**	31.5 (9.0)	22.4 (13.4)	9.1 (–0.8, 18.4)
Overall pain since termination, median (range)	2.1 (0–9.5)	1.6 (0–9.8)	NS	0.4 (0.1–6.2)	1.4 (0–6.0)	NS
Most severe pain since termination	3.9 (0–10)	2.5 (0–9.9)	NS	1.5 (0.2–9.9)	3.1 (0–9.2)	NS

Source: Table 2.23, p59 of the submission

CI = confidence interval; MTOP = Medical termination of pregnancy; n = number of participants reporting data; NS = not significant; SD = standard deviation; STOP = Surgical termination of pregnancy.

Bold indicates statistically significant results.

Table 7: Medical sequelae at Week 8 following the abortion in Ashok et al. (2002)

	MTOP n/N (%)	**STOP n/N (%)**	**RD (95% CI)**
Contacted family doctor	30/158 (19.0)	43/207 (20.8)	-1.8 (-10, 6.5)
Presumed pelvic infection requiring antibiotic treatment	7/158 (4.4)	17/207 (8.2)	-3.8 (-8.7, 1.1)
Psychiatric and psychological morbidity	10/158 (6.3)	10/207 (4.8)	-1.9 (-7.2, 3.4)
Abnormal abdomino–pelvic pain and or vaginal bleeding	5/158 (3.2)	8/207 (3.9)	-0.7 (-4.5, 3.1)
Other morbidity	8/158 (5.1)	8/207 (3.9)	1.2 (-3.1, 5.5)
Unplanned hospital visit	6/203 (3.0)	9/242 (3.7)	-0.8 (-4.1, 2.6)
Hospital readmission	1/203 (0.5)	7/242 (2.9)	**-2.4 (-4.7, -0.1)**
Time taken to return to normal activity, median (range)	2.5 days (0–14)	2.5 days (0–20)	NS
Time taken to return to work, median (range)	2.0 days (0–21)	2.0 days (0–21)	NS

Source: Table 2.22, p59 and Table 2.24, p60 of the submission.

CI = confidence interval; MTOP = Medical termination of pregnancy; n = number of participants reporting data; N = total participants in group; NS = not significant; RD = risk difference; STOP = Surgical termination of pregnancy

Note: When the confidence intervals include zero, the differences between the two groups are not significant at the 5% level.

Bold indicates statistically significant results.

6.27 At 2–3 weeks post-procedure, women randomised to MTOP reported more bleeding days, and higher total vaginal bleeding score than women randomised to STOP. At 8-week post-procedure, rates of consultation with family doctor, antibiotic treatment for presumed pelvic infection, unplanned hospital visit, and other complications or morbidities were similar between the MTOP and STOP groups; however, significantly

more women in the STOP were re-admitted following termination, with reasons for re-admission not reported. Outcomes related to time to return to work and normal activity were also similar.

6.28 Only three supportive studies reported data on medical sequelae following MTOP. In Winikoff et al. (2012), 14% of the women with a gestational age 64–70 days visited the emergency department, and the mean number of days of work or school missed due to MTOP was 1.8 days. In Dzuba et al. (2020), 2.6% of the women with gestational age 64–70 days visited the emergency department, and 1.3% had unplanned clinic visits. In Tan et al. (2018), 5.6% of the women had unplanned clinic visits. Notably, outcomes related to unplanned hospital admission, doctor consultation, and time to return to work/normal activity were not consistently reported across all supportive studies.

Patient preferences and acceptability of procedure

6.29 In Ashok et al. (2002), there was statistically significantly greater preference for MTOP compared with STOP prior to termination (72% vs. 28%). However, following abortion, 70% of those who underwent a MTOP and 79% who underwent a STOP would opt for the same method in the future, noting that the post-termination preference responses were based a small number of included participants.

Comparative harms

6.30 The safety data in Ashok et al. (2002) were based on all included participants at gestational age ≥64 days, without stratification by gestational age and are summarised in Table 8.

Table 8: Summary of key adverse events in Ashok et al. (2002)

Adverse events	MTOP n/N (%)	STOP n/N (%)	RD (95% CI)
Randomised			
Nausea	128/186 (69.2)	50/180 (27.8)	**41.0 (31.7, 50.4)**
Vomiting	91/186 (49.2)	15/180 (8.3)	**40.6 (32.4, 48.8)**
Diarrhoea	79/186 (42.5)	8/180 (4.5)	**38.0 (30.3, 45.7)**
Abdominal pain	182/186 (97.8)	163/180 (90.6)	**7.3 (2.5, 12.0)**
Vaginal bleeding	178/186 (97.8)	166/180 (94.3)	3.5 (-1.4, 8.4)
Tiredness	159/186 (85.5)	127/180 (70.9)	**14.9 (6.6, 23.3)**
Headache	51/186 (27.6)	28/180 (15.6)	**11.9 (3.5, 20.2)**
Hot flushes	74/186 (40.0)	21/180 (11.7)	**28.1 (19.7, 36.6)**
Dizziness	82/186 (44.3)	39/180 (21.0)	**22.4 (13.1, 31.8)**
Preference			
Nausea	9/15 (60.0)	11/60 (18.3)	**41.7 (15.0, 68.3)**
Vomiting	7/15 (46.7)	3/60 (5.0)	**41.7 (15.8, 67.5)**
Diarrhoea	7/15 (46.7)	0/60 (0)	**46.7 (21.4, 71.9)**
Abdominal pain	15/15 (100)	53/60 (88.3)	**11.7 (3.5, 19.8)**
Vaginal bleeding	12/15 (80.0)	53/60 (91.4)	-8.3 (-30.1, 13.5)
Tiredness	10/15 (66.7)	45/60 (75.0)	-8.3 (-34.6, 17.9)
Headache	6/15 (40.0)	4/60 (6.7)	**33.3 (7.8, 58.9)**
Hot flushes	5/15 (33.3)	5/60 (8.5)	**25.0 (0.1, 49.9)**
Dizziness	7/15 (46.7)	10/60 (16.7)	**30.0 (3.0, 57)**

Source: Table 2.36, p69 of the submission.

CI = confidence interval; MTOP = Medical termination of pregnancy; n = number of participants reporting data; N = total participants in group; RD = risk difference; STOP = Surgical termination of pregnancy
Bold indicates statistically significant results.

6.31 In Ashok et al. (2002), women undergoing MTOP reported higher rates of nausea, vomiting, diarrhoea, hot flushes, dizziness, headache, and abdominal pain, compared with those undergoing STOP. This was consistent with the safety data reported in the 2013 PBAC submission. Four women (2.0%) in the MTOP group required syntometrine to control bleeding, and two women (0.8%) women in the STOP group reported blood loss of 500 mL, with one woman (0.4%) woman requiring a blood transfusion.

6.32 In the supportive studies, the most common reported adverse events associated with MTOP were fever/chills, nausea, vomiting, and diarrhoea, although the frequency of these events varied across studies. Most adverse events were considered mild or moderate, based on Sanhueza Smith et al. (2015).

Benefits/harms

6.33 A benefits and harms table is not presented as the submission made a claim of non-inferiority.

Clinical claim

6.34 The ESC considered that the submission's claim that MTOP using MS-2 Step is non-inferior in terms of effectiveness compared to STOP among women with gestation age of 64–70 days, was supported by the evidence.

6.35 The submission claimed both medical and surgical abortions are safe and acceptable, but the safety and tolerability of the methods are different and not directly comparable. The ESC considered that this was reasonable.

6.36 The PBAC considered that the claim of non-inferior comparative effectiveness was reasonable.

6.37 The PBAC considered that the claim that both MTOP and STOP were safe, but not directly comparable was also reasonable.

Economic analysis

6.38 The submission presented a simple comparison of costs associated with MTOP and STOP, including pre-procedure, delivery, post-procedure follow-up, and management of complications. This approach was consistent with that used in 2013 PBAC submission (Mifepristone and misoprostol, PSD, March 2013 PBAC meeting).

6.39 The unit costs for the resources used in the economic evaluation, as well as the comparison of the costs associated with MTOP versus STOP are presented in Table 9.

Table 9: Cost analysis comparing costs associated with MTOP versus costs associated with STOP

Resource	Unit cost	Source	MTOP		STOP	
			Average quantity per patient	Weighted cost per patient	Average quantity per patient	Weighted cost per patient
Resources used in lead-up						
Level B initial consultation with GP for referral	$43.90	MBS Item 23	0.6	$26.34	0.6	$26.34
Level C consultation with provider of TOP	$84.90	MBS Item 36	1	$84.90	1	$84.90
Serum hCG quantitation	$29.35	MBS Item 73529	1	$29.35	1	$29.35
Ultrasound	$40.10	MBS Item 55703	0.5	$20.05	1	$40.10
Sub-total				$160.64		$180.69
Resources used in delivering TOP						
Pre-anaesthesia consultation (≤ 15 minutes)	$50.95	MBS Item 17610	0	$0.00	56%	$28.54
Initiation of management of anaesthesia	$92.40	MBS Item 20940	0	$0.00	56%	$51.75
Anaesthesia time (2 units – 16-20 minutes)	$46.20	MBS Item 23025	0	$0.00	56%	$25.88
Evacuation of the contents of the gravid uterus	$254.30	MBS Item 35643	0	$0.00	56%	$142.43
Admission to private hospital facility - AR-DRG O05 (abortion with OR procedure)	$1,113.22[a,b]	Table 7: Private hospital separations - AR-DRG, 2022-23	0	$0.00	40%[c]	$448.92
Admission to public hospital facility - AR-DRG O05 (abortion with OR procedure)	$4,018.00[b]	Cost weights for AR-DRG Version 11.0, 2020-21	0	$0.00	44%	$1,767.58
Mifepristone + misoprostol (MS-2 Step)	$391.06	PBS Item 10211K	1	$391.06	0	$0.00
Paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet	$17.09	PBS Item 12022R	0.8	$13.67	0	$0.00
Metoclopramide 10 mg tablets	$16.48	PBS Item 1207M	0.8	$13.18	0	$0.00
Sub-total				$417.92		$2,465.09
Resources used in follow-up after TOP						
Level B consultation with provider of TOP	$43.90	MBS Item 23	1	$43.90	0	$0.00
Serum hCG quantitation	$29.35	MBS Item 73529	1	$29.35	0	$0.00
Ultrasound	$40.10	MBS Item 55703	0.1	$4.01	0	$0.00
Sub-total				$77.26		$0.00
Resources used to manage complications of TOP						
Admission to public hospital facility -AR-DRG O04 (post-partum or post-abortion with OR procedure)	$9,694.11[b]	Cost weights for AR-DRG Version 11.0, 2020-21	0.029	$281.13	0.00	$0.00
Sub-total				$281.13		$0.00
Total costs			$936.95		$2,645.78	
Difference (MTOP – STOP)			**-$1,708.83**			

Source: Table 3.2, p85 and Table 3.3, p86 of the submission.

AR-DRG = Australian Refined Diagnosis Related Group; GP = general practitioner; hCG = human chorionic gonadotropin; MBS = Medicare Benefits Schedule; MTOP = medical termination of pregnancy; OR = operating room; PBS = Pharmaceutical Benefits Scheme; STOP = surgical termination of pregnancy; TOP = termination of pregnancy.

[a] The submission estimated AR-DRG O05 unit costs of $1,477 for private inpatient admissions and $959 for private day-only admissions.

[b] Costs for DRGs associated with abortion or revision procedures were inflated to 2026 dollars using Australian Bureau of Statistics (ABS) health-related Consumer Price Index (CPI) data.
[c] Based on the multiplication of 56% and 72%, whereby the submission assumed that of the 56% of the patients undergoing STOP in the private setting, 72% were admitted to the hospital or daycare.
Italics corrected during evaluation to reflect correct MBS fee for Item 36 ($84.90 instead of $89.40).

6.40 The submission estimated the total cost of MTOP with MS-2 Step to be $936.95, compared with $2,645.78 for STOP, resulting in an estimated cost saving of $1,708.83. The saving was largely driven by differences in resources used to delivery TOP, partially offset by higher follow-up and complication-related costs associated with MTOP.

6.41 The ESC noted that the magnitude of the estimated cost saving was uncertain as:

- The utilisation of consultation with GP or TOP provider (60%) and ultrasound (50%) was largely based on sponsor's assumptions and was likely to be underestimated, especially in the MTOP arm. Women accessing MTOP via telehealth typically require two medical appointments, and may also require an ultrasound, consistent with Clinical Services: Abortion by Telehealth by MSI Australia[6]. Increased utilisation of resources in the lead-up would reduce the estimated cost savings (refer to Table 10).
- The submission estimated that 56% of STOP procedure were performed in the private sector based on 2025 MBS service volumes (Item 35643) and hospital separation data from the 2020–21 National Hospital Cost Data Collection (NHCDC) Public Sector Report, assuming that 16% of public hospital separations were related to private patients[7]. However, this estimate differed from jurisdiction-specific data, with Western Australian[8] and Victorian[9] data indicating substantially higher proportions of procedures occurring in private facilities (86% and 72%, respectively). Furthermore, the use of data from different years and sources added uncertainty. Increasing this proportion would reduce the estimated cost savings (refer to Table 10).
- The unit cost estimated for private hospital admission under Australian Refined Diagnosis Related Group (AR-DRG) O05 ($1,113; based on weighted cost of 70%

[6] MSI Australia (2024), 'Clinical services Telehealth', Available at: https://www.msiaustralia.org.au/accessible/clinical-services-teleabortion/
[7] Independent Health and Aged Care Pricing Authority, 'National Hospital Cost Data Collection (NHCDC) Public Sector Cost Weights AR-DRG Version 11.0 2020-2021', Available at: https://www.ihacpa.gov.au/resources/national-hospital-cost-data-collection-nhcdc-public-sector-report-2020-21
[8] Galrao M., Hutchinson M, Joyce A. (2019), 'Induced abortions in Western Australia 2016-2018: in brief', Sixth Report of the Western Australian Abortion Notification System, Department of Health, Western Australia. Available at: https://www.parliament.wa.gov.au/publications/tabledpapers.nsf/displaypaper/4112487ca26b269c9f05f65448258a2900029e7a/$file/tp-2487.pdf
[9] Marzan M., Johson E., Moore P., et al (2024), 'Changes in the numbers of hospital-based abortions and outpatient early medical abortions in Victoria, 2012–22: a retrospective cohort study', Med J Aust 220(3):145-153.

day care ($959) and 30% inpatient hospitalisation ($1,477)) was considerably lower, and likely underestimated, compared with the corresponding public hospital cost ($4,018). It is more appropriate to apply AR-DRG costs derived from the National Public Sector Cost Weights for admitted services, as set out in the "Manual of resource items and their associated unit costs"[10]. Use of the public hospital cost for private admissions would substantially increase the estimated cost savings associated with MTOP.

- The submission assumed approximately 72% of private patients would be admitted to a private hospital or day procedure unit. However, this assumption was inappropriate, as the calculation did not account for the remaining patients seeking a STOP (refer to Table 10).
- Based on the RANZCOG Clinical Guideline, cervical priming with misoprostol should be offered for surgical abortion up to 14 weeks to reduce the risk of incomplete abortion, ongoing pregnancy, future cervical insufficiency and preterm birth, and reduce the need for additional mechanical dilatation. However, misoprostol is not available as a single product on the PBS. Including the cost of MS-2 Step (composite pack containing misoprostol) in the STOP arm would further increase the estimated cost savings associated with MTOP.
- The assumption that no resources would be used in follow-up after STOP or to manage complications associated with STOP was not reasonable, but ESC noted that inclusion of these costs would further increase the estimated cost savings associated with MTOP.

6.42 Results of sensitivity analyses examining alternate scenarios are presented in Table 10.

[10] Commonwealth of Australia, 'Manual of resource items and their associated unit costs', version 5, Available at: https://www.pbs.gov.au/info/industry/useful-resources/manual

Table 10: Results of sensitivity analyses

Parameter varied	Total costs for MTOP	Total costs for STOP	Difference (MTOP – STOP)	% change in cost saving
Base case[a]	$936.95	$2,645.78	-$1,708.83	-
One-way sensitivity analyses				
(i) Proportion of patients requiring admission to manage complications of TOP (base case: 2.9% for MTOP and 0% for STOP [difference = 2.9%])				
• 5.8% for MTOP and 0% for STOP [difference = 5.9%]	$1,218.07	$2,645.78	-$1,427.70	-16.5%
• Threshold analysis: 20.5% for MTOP and 0% for STOP [difference = 20.5%]	$2,645.78	$2,645.78	$0	100%
(ii) Proportion of women undergoing STOP as private patients admitted to a hospital/day facility (base case: 72%)				
• increased to 90%	$936.95	$2,758.01	-$1,821.06	+6.6%
• decreased to 50%	$936.95	$2,508.61	-$1,571.66	-8.0%
(iii) Proportion of women undergoing MTOP who purchase analgesic and anti-emetic (base case: 80%)				
• increased to 100%	$943.66	$2,645.78	-$1,702.12	-0.4%
• decreased to 60%	$930.23	$2,645.78	-$1,715.55	+0.4%
(iv) Proportion of women undergoing MTOP who receive an ultrasound in the lead-up to MTOP (base case: 50%)				
• increased to 100%	$957.00	$2,645.78	-$1,688.78	-1.2%
(v) Proportion of women undergoing STOP as private patients (base case: 56%)				
• increased to 86%	$936.95	$1,814.23	-$877.28	-48.7%
• increased to 72%	$936.95	$2,202.40	-$1,265.45	-25.9%
(vi) Proportion of women requiring Level B initial consultation with GP prior to MTOP (base case: 0.6)				
• increased to 1	$954.51	$2,645.78	-$1,691.27	-1.0%
(vii) Using public hospital admission cost for private hospitalisation (base case: $1,113.22)				
• increased to $4,018	$936.95	$3,817.17	-$2,880.22	+68.5%
Multi-way sensitivity analyses				
Applying the least favourable (for MTOP) values for parameters as made in (i) – (iv)	$1,244.84	$2,508.61	-$1,263.77	-26.0%
Applying the least favourable (for MTOP) values for parameters as made in (ii) – (vii) & a 5.8% difference in complication rate	$1,262.40	$2,852.66	-$1,590.26	-6.9%

Source: Table 3.4, p87 of the submission

MTOP = medical termination of pregnancy; STOP = surgical termination of pregnancy; TOP = termination of pregnancy.

[a] *Corrected during evaluation to reflect correct MBS fee for Item 36 ($84.90 instead of $89.40).*

Italics added during evaluation.

6.43 Consistent with the March 2013 and July 2014 PBAC submission, the sensitivity analyses comparing costs for women at 64–70 days gestation demonstrated that MTOP remains less costly than STOP. Notably, the results were highly sensitive to the proportion of STOP procedures performed in the private sector. Increasing this proportion from 56% to 86%, reduced the cost saving by 49% due to differences in the private versus public costs applied in the submission.

6.44 A threshold analysis was also conducted during the evaluation to determine the magnitude of difference required in complication rate at which MTOP would no longer be cost saving compared with STOP. This was calculated to be 20.5%, which is substantially higher and unlikely, based on the evidence available to date.

Drug cost/patient: $391.06

6.45 The requested DPMQ for a pack of MS-2 Step was $391.06. This was unchanged from the current DPMQ.

6.46 The total cost of MTOP with MS-2 Step was estimated to cost $936.95 per patient, compared with $2,645.78 for STOP, although the magnitude of the estimated cost saving was uncertain (see paragraph 6.41).

Estimated PBS usage & financial implications

6.47 This submission was not considered by DUSC.

6.48 Consistent with the July 2013 and March 2014 PBAC submissions, the submission relied on an epidemiological approach to estimate the financial impact of listing MS-2 Step for termination of pregnancy between 64–70 days' gestation.

6.49 Table 11 summarises the key inputs and data sources to estimate the utilisation of MS-2 Step.

Table 11: Data sources and parameter values applied in the utilisation and financial estimates

Parameter	Value applied and source	Comment
Number of women aged 15–44	5.7 million in 2027 to 5.9 million in 2032; based on ABS Table 3222.0 Series B, Females aged 15 to 44	-
Incidence of TOP	1.3%; based on South Australian Abortion Reporting Committee, April 2025	This estimate relied solely on South Australian data and may not reflect variation in incidence across other jurisdictions (refer to paragraph 6.50). Variation in incidence rate was tested in sensitivity analyses.
Proportion of TOP in first trimester	91.1%; based on South Australian Abortion Reporting Committee, April 2025	Similar to the incidence rate, this estimate relied solely on South Australian data (refer to paragraph 6.50). Variation in the proportion rate was tested in sensitivity analyses.
Proportion of TOP in first trimester between 64 and 70 days	5%; based on previous PBAC submissions for MS-2 Step (July 2013, March 2014)	It was unclear how the estimate was derived. It was noted that Western Australia data indicated that 11.8% of abortions occur between 64 and 98 days' gestation[a].
Uptake rate	60% in Year 1 increasing to 100% in Year 5; based on sponsor's assumption	No data or evidence were provided to support the uptake rates. Uptake in the initial years may be higher than the assumed, given the changes enabling any healthcare practitioner with appropriate qualifications and training to prescribe MS-2 Step. Conversely, a 100% uptake rate in later years is likely to overestimate use, as not all women would choose MTOP over STOP.
MS-2 Step	$391.06; requested DPMQ	-
MBS costs associated with MTOP[b]	$237.90; based on the calculation detailed in Table 9	Consistent with the economic evaluation.
MBS costs associated with STOP[b]	$429.28; based on the calculation detailed in Table 9	Consistent with the economic evaluation.

Source: Table 4.1, p89; Section 4.2, p90; Section 4.3, p92; Table 4.10, p95 of the submission.
ABS = Australian Bureau of Statistics; DPMQ = Dispensed Price for Maximum Quantity; MBS = Medicare Benefit Schedule; MTOP = medical termination of pregnancy; STOP = surgical termination of pregnancy; TOP = termination of pregnancy.
[a] Derived from the Western Australia abortion data that there were 7,816 abortions in 2018, with 7,342 abortions conducted at <14 weeks gestation and 6,417 occurring at ≤9 weeks (Wright SM et al., 2021).
[b] Corrected during evaluation to reflect correct MBS fee for Item 36 ($84.90 instead of $89.40).

6.50 While the estimates for the incidence of TOP (1.3%) and proportion of TOP occurring in first trimester (91.1%) were based on the most recent publicly available dataset, they relied solely on South Australian[11] data and may not reflect variation across other jurisdictions. In 2018, Western Australian reported a slightly higher abortion rate of 14.3 per 1,000 women aged 15–44 years, with 93.9% of the abortions conducted in the first trimester[12]. In addition, a study utilising National Hospital Morbidity and PBS data estimated an abortion incidence rate of 1.73% for the 2017–2018 period[13]. While the source for the proportion of first-trimester TOP occurring between 64 and 70 days'

[11] South Australian Abortion Reporting Committee, (2025), 'Annual Report for the year 2024', Available at: https://www.preventivehealth.sa.gov.au/assets/downloads/abortion-reporting/South-Australian-Abortion-Reporting-Committee-Report-2024_FINAL.pdf
[12] Wright SM., Bateson D., McGeechan K. (2021), 'Induced abortion in Australia: 2000-2020', Family Planning NSW: Ashfield, Australia, Available at: https://www.fpnsw.org.au/sites/default/files/assets/Induced-Abortion-in-Australia_2000-2020.pdf
[13] Keogh LA., Gurrin LC., Moore P. (2021), 'Estimating the abortion rate in Australia from National Hospital Morbidity and Pharmaceutical Benefits Scheme data', Med J Aust 215(8):375-376.

gestation was untraceable, it was not considered unreasonable by the evaluation, noting that Western Australia data indicated that 11.8% of abortions occur between 64 and 98 days' gestation[12].

6.51 The uptake rates were uncertain, as no data or evidence were provided to support the assumptions used in the submission. Uptake in the initial years may be higher than assumed, noting recent changes that enable any appropriately qualified and trained healthcare practitioner to prescribe MS-2 Step. Conversely, a 100% uptake rate in later years is likely to overestimate use, as not all women would choose MTOP over STOP. Furthermore, based on Ashok et al. (2002), prior to termination, 80% of the women had a preference for a TOP method, whereby 72% (n=253) preferred MTOP and 28% (n=98) preferred STOP. Following termination, 70% (n=47) of the women who underwent MTOP and 79% (n=76) of the women who underwent STOP would choose the same method in the future.

6.52 The PSCR and pre-PBAC response acknowledged the limitations in estimating the patient population and stated that any increased utilisation versus forecast will result in additional savings to health budgets due to the cost saving of MTOP compared to STOP.

6.53 Table 12 presents the estimated financial implications of listing of MS-2 Step.

Table 12: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of patients treated	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Estimated financial implications of MS-2 Step (including analgesics and anti-emetics[a])						
Cost to PBS/RPBS less copayments	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]
Estimated financial implications to MBS for MTOP and STOP						
Cost to MBS for MTOP	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]
Cost to MBS for reduced STOP	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]
Net financial implications						
Net cost to PBS/RPBS	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]
Net cost to MBS	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]
Net cost to PBS/RPBS/MBS	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]

Source: Table 4.2, p90; Table 4.5, p91; Table 4.6, p92; Table 4.7, p93; 'Attachment 4.1' workbook to the submission.
MBS = Medicare Benefit Schedule; MTOP = medical termination of pregnancy; STOP = surgical termination of pregnancy; PBS = Pharmaceutical Benefits Scheme, RPBS = Reparation Pharmaceutical Benefits Scheme.
Corrections were made to the number of services per patient per year and the population split in '7. Net changes- MBS' worksheet in 'Attachment 4.1' workbook based on Table 9. In addition, the MBS fee for Item 36 was corrected to $84.90 (previously $89.40).
[a] Cost of analgesia and anti-emetics was $15 in Years 1–5 and $30 in Years 4-6
The redacted values correspond to the following ranges:
[1] *500 to < 5,000*
[2] *$0 to < $10 million*
[3] *net cost saving*

6.54 The total cost to the PBS/RPBS of listing MS-2 Step for women with a gestational age of 64–70 days was estimated to be $0 to < $10 million in Year 6, and a total of $0 to < $10 million in the first six years of listing. The total cost to the PBS/RPBS/MBS over 6 years was estimated to be $0 to < $10 million. The ESC noted that the copayment distribution for the analgesics and antiemetics did not match that applied

to MS-2 Step. Correction of this resulted in a small increase to net cost to the PBS/RPBS to $0 to < $10 million (and to the net cost to the PBS/RPBS/MBS to $0 to < $10 million) over the first 6 years of listing.

6.55 The financial estimates were sensitive to assumptions regarding the incidence of TOP, the proportion occurring in the first trimester, and the proportion between 64 and 70 days' gestation, with higher values substantially increasing the estimated financial impact, as presented in Table 13.

Table 13: Sensitivity analyses – total cost to the PBS/RPBS/MBS

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	% Change
Base case	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	-
Incidence of TOP (base case: 1.3%)							
Decreased to 1.04%	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	-[redacted]%
Increased to 1.56%	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	+[redacted]%
Proportion of TOP in 1st trimester (base case: 91.1%)							
Decreased to 82%	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	-[redacted]%
Increased to 100%	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	+[redacted]%
Proportion of TOP in first trimester between 64 and 70 days' gestation (base case: 5%)							
Decreased to 4%	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	-[redacted]%
Increased to 6%	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	+[redacted]%

Source: Table 4.13, p97 of the submission and 'Attachment 4.1' excel workbook to the submission.
TOP = termination of pregnancy.
The redacted values correspond to the following ranges:
[1] $0 to < $10 million

6.56 The ESC noted that MS-2 Step may be used outside the requested listing, including in women undergoing MTOP between 10^{+1} and 20 weeks' gestation in line with conditional recommendation in the RANZCOG Clinical Guideline.

6.57 Additionally, misoprostol with or without mifepristone may be used to assist in the medical evacuation of the conceptus of pregnancy following incomplete miscarriage. As misoprostol is not listed on the PBS as a single product (it is only available as a composite pack), there is potential for off-label use of MS-2 Step.

Quality Use of Medicines

6.58 The submission stated that the sponsor has developed and maintained prescriber education and patient support tools to ensure MS-2 Step is used safely, effectively, and in accordance with its approved indication.

For more detail on PBAC's view, see section 7 PBAC outcome.

7 PBAC Outcome

7.1 The PBAC recommended extending the listing of mifepristone and misoprostol (hereafter referred to as MS-2 STEP) for the termination of intra-uterine pregnancy from use up to 63 days of gestation to use up to 70 days of gestation. The PBAC considered that medical termination of pregnancy (MTOP) using MS-2 STEP was non-inferior in terms of effectiveness compared to surgical termination of pregnancy (STOP) among patients with a gestation age of 64 to 70 days. The PBAC also considered

that the cost comparison of MTOP and STOP was appropriate, noting that MTOP with MS-2 STEP was cost saving. The PBAC considered that the estimated financial impact of extending the restriction for MS-2 STEP was reasonable.

7.2 The PBAC noted the consumer input was also supportive of extending the restriction to allow MS-2 STEP to be prescribed up to 70 days gestation. The PBAC noted that the input described how the extension would improve equity and increase access to timely care for patients in rural and remote areas and those facing delays in finding an available prescriber, referral and ultrasounds.

7.3 The PBAC noted that the requested expansion in the eligibility criteria aligned with The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) Clinical Guideline for abortion care (2025)[14].

7.4 The PBAC noted that the submission was based on a sub-group analysis of patients with a gestational age between 64 and 70 days from the Ashok et al (2022) trial, which compared MTOP using MS-2 STEP with STOP. The PBAC considered that the comparison with STOP was appropriate.

7.5 The PBAC noted that MTOP was associated with no statistically significant difference in complete abortion/intra-uterine evacuation compared to STOP (97.1% vs 100%; RD = -2.9%; 95% CI: -6.0, 0.3) for patients with a gestation age of 64 to 70 days. The PBAC considered that MTOP using MS-2 STEP was non-inferior compared to STOP in terms of effectiveness, noting that a small proportion of patients would require a follow-up procedure following MTOP.

7.6 In terms of safety, the PBAC noted that although MTOP and STOP were not comparable, both were considered safe.

7.7 The PBAC noted that the submission presented a simple comparison of the costs associated with MTOP using MS-2 STEP and STOP and that this approach was consistent with previous submissions for MS-2 STEP. The PBAC noted that the base case included additional follow up costs for MTOP. Overall, MTOP was cost saving compared to STOP in the base case presented in the submission, as well as for all alternate scenarios presented (see Table 10).

7.8 In terms of the utilisation and financial impact, the PBAC considered that the estimates provided in the submission were reasonable, noting that there were limitations in estimating the patient population. The PBAC noted that any increased utilisation of MS-2 STEP over STOP would result in additional savings to health budgets.

7.9 The PBAC noted that the proposed restriction change for use up to 70 days gestation was appropriate. The PBAC also advised that a Prescribing Instruction should be added

[14] Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), 2025, 'Clinical Guideline for Abortion Care: An evidence-based guideline on abortion care in Australia and Aotearoa New Zealand'. Available at: https://ranzcog.edu.au/wp-content/uploads/Clinical-Guideline-Abortion-Care.pdf.

stating that the patient must undertake a follow-up pregnancy test to confirm MTOP. The timing of the follow-up pregnancy test would be up to the discretion of the treatment practitioner. The PBAC advised that MS-2 STEP is suitable for prescribing by medical practitioners, nurse practitioners and midwives.

7.10 The PBAC noted that its recommendation was on a cost-comparison basis and advised that, because MTOP using MS-2 STEP is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over STOP, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.

7.11 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:
Recommended

8 Recommended listing

8.1 Amend existing listing as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
MIFEPRISTONE (&) MISOPROSTOL					
mifepristone 200 mg tablet [1] (&) misoprostol 200 microgram tablet [4], 1 pack	10211K MP MW NP	1	1	0	MS-2 Step

Restriction Summary / Treatment of Concept		
Concept ID (for internal Dept. use)		**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
		Prescriber type: ☒Medical Practitioners ☒Nurse practitioners ☒Midwives
		Restriction type: ☒Authority Required (Streamlined) [existing code]
Prescribing rule level		**Administrative Advice:** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.
		Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
		Administrative Advice: No increase in the maximum number of repeats may be authorised.
		Episodicity: [blank]
		Severity: [blank]
		Condition: Termination of an intra-uterine pregnancy
		Indication: Termination of an intra-uterine pregnancy
		Treatment Phase: [blank]
		Clinical criteria:
		The condition must be an intra-uterine pregnancy of up to 70 days gestation
		Prescribing Instructions: Patient must undertake a follow-up pregnancy test to confirm completion of the termination. Confirmation of termination must be documented in the patients' medical records.

These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.