Mifepristone and misoprostol: predicted versus actual analysis

Drug utilisation sub-committee (DUSC)

September 2016

## Abstract

### Purpose

To compare the predicted and actual use of mifepristone and misoprostol supplied through the PBS for medical termination of pregnancy (MTOP).

### Listing on the Pharmaceutical Benefits Scheme (PBS)

Mifepristone and misoprostol were PBS listed for the termination of an intra-uterine pregnancy on 1 August 2013.

When recommending this listing the Pharmaceutical Benefits Advisory Committee (PBAC) considered that mifepristone and misoprostol for MTOP allows choice for women who have decided to undergo a termination and its availability through the PBS was considered unlikely to result in an increase in overall terminations of pregnancy.

### Data Source / methodology

The number of MTOPs based on PBS claims of mifepristone and misoprostol was sourced from the Department of Human Services (DHS) date of supply data. The number of surgical terminations of pregnancy (STOPs) in the private sector was estimated from publicly available DHS Medicare statistics data. The number of STOPs in the public sector was estimated from Activity Based Funding (ABF) Cost Weights that estimate the number of hospital separations.

### Key Findings

* The proportion of TOPs undertaken by the medical method has been lower than predicted.
* Data available to date suggests the introduction of mifepristone and misoprostol on the PBS has not increased the number of TOPs in Australia per year.

# Purpose of analysis

To compare the predicted and actual use of mifepristone and misoprostol supplied through the PBS for medical termination of pregnancy (MTOP).

# Background

## Pharmacology, dosage and administration

Mifepristone acts by blocking the effects of progesterone, a hormone needed for pregnancy to continue. Mifepristone can therefore be used to terminate a pregnancy. It is given in combination with misoprostol, a prostaglandin analogue that induces contractions of the smooth muscle and relaxation of the cervix. These properties help open the cervix and push out the contents of the uterus. It is necessary to take the mifepristone tablet first and then 36-48 hours later take the misoprostol tablets.[[1]](#footnote-1)

Mifepristone can also be used for preparation for the action of registered prostaglandin analogues that are indicated for the termination of pregnancy for medical reasons beyond the first trimester.[[2]](#footnote-2) Misoprostol can also be used for treatment and prevention of some gastric and duodenal ulcers.[[3]](#footnote-3) Use for these indications is beyond the scope of this review.

The current Product Information (PI) and Consumer Medicine Information (CMI) are available from the TGA (Product Information) and the TGA (Consumer Medicines Information).

## PBS listing details (as at August 2016)

Table 1: PBS listing of mifepristone and misoprostol

| Item | Name, form & strength, pack size | Max. quant. | Rpts | DPMQ | Brand name and manufacturer |
| --- | --- | --- | --- | --- | --- |
| 10211K | MIFEPRISTONE (&) MISOPROSTOL  mifepristone 200 mg tablet [1] (&) misoprostol 200 microgram tablet [4], 1 pack | 1 | 0 | $311.26 | MS-2 Step |

Source: the PBS website.

### Current Restriction

Mifepristone and misoprostol are supplied through the PBS in a composite pack under the brand name MS-2 Step. MS-2 Step is PBS listed under an Authority Required listing for termination of an intra-uterine pregnancy of up to 63 days of gestation. Patients must be treated by a prescriber who is registered with the MS 2 Step Prescribing Program.

For details of the current PBS listing refer to the PBS website.

### Date of first listing on PBS

Mifepristone and misoprostol were PBS listed for the termination of an intra-uterine pregnancy of up to 49 days of gestation on 1 August 2013.

### Changes to listing

From August 2013 to March 2015 mifepristone and misoprostol were listed as separate PBS items. From February 2015 mifepristone and misoprostol were listed as a composite pack, for the termination of an intra-uterine pregnancy. The listing was also extended from 49 to up to 63 days of gestation. The individual items were delisted from April 2015.

Prior to 1 August 2013, misoprostol was listed for the treatment of patients with peptic ulcer disease, duodenal ulcer and gastric ulcer. Due to the statutory price reduction triggered by the listing of the new brand of misoprostol, the original brand was delisted.

Current PBS listing details are available from the PBS website.

## Relevant aspects of consideration by the Pharmaceutical Benefits Advisory Committee (PBAC)

At its March 2013 meeting, the PBAC recommended the listing of mifepristone and misoprostol for termination of an intra-uterine pregnancy of up to 49 days’ gestation on the premise of non-inferior effectiveness against surgical termination of pregnancy.

The PBAC noted that in clinical practice, outlined in the clinical management algorithm, the decision between medical termination of pregnancy and surgical termination of pregnancy comes only after a woman has made the decision to undergo a termination. For this reason, the PBAC considered that the availability of mifepristone and misoprostol through the PBS was not likely to increase the overall number of procedures undertaken. This was supported by utilisation data from other countries.

The results of the economic analysis showed that medical termination of pregnancy was less costly than surgical termination of pregnancy to the whole of health budget (both Commonwealth and state hospital and community costs).

For further details refer to the Public Summary Document from the March 2013 PBAC meeting.

At its July 2014 meeting, the PBAC recommended the listing of a composite pack containing mifepristone and misoprostol 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-approved indication. The listing of the composite pack was intended to replace the listings of the components, with an amended restriction consistent with revised TGA indications.

The submission re-presented the same estimates as in the March 2013 submission.

The PBAC noted that the utilisation of mifepristone and misoprostol had been lower than expected since PBS listing on 1 August 2013. The PBAC noted the sponsor’s claim that the primary barrier to utilisation related to medical indemnity insurance for clinicians wanting to provide MTOP. As matters of professional indemnity are beyond the PBAC’s remit, the Committee did not comment on this claim. Nonetheless, the PBAC considered that in view of utilisation patterns to date, and the fact that the Committee had accepted that MTOP would be cost-saving compared with STOP, it was not likely that utilisation of the composite pack would increase to the point where it would pose a financial risk to the Commonwealth.

For further details refer to the Public Summary Document from the July 2014 PBAC meeting.

## Approach taken to estimate utilisation

Key assumptions in estimating the use of mifepristone and misoprostol through the PBS were:

* that the availability of mifepristone and misoprostol would not increase the total number of TOPs in Australia; and
* that the proportion of TOPs undertaken by the medical method would be 25% in year 1 of listing increasing to 45% in year 5 of listing.

The submission recognised that there are no national statistics on TOPs in Australia. The submission used the following data sources to estimate the total number of TOPs of gestational age ≤ 49 days in the 2011/2012 financial year and the associated rate of TOPs in Australian women aged 15-44:

* MBS data for use of Item 35643 (evacuation of a gravid uterus), which was used to estimate the number of STOPs conducted in the private sector;
* AR-DRG cost weights with details of hospital separations for STOP, which were used to estimate the number of STOPs conducted in the public sector;
* Details from a Parliamentary Research Brief[[4]](#footnote-4) that estimated the proportion of TOPs conducted in the public sector for private patients;
* A response from the Department of Health and Ageing to a question on notice (Question E12-068)[[5]](#footnote-5) in regard to budget estimates for financial year 2012/2013 that provided details of the number of women who were prescribed mifepristone in each calendar year from 2006 to 2011 under the TGA’s Authorised Prescriber program;
* Estimates of Australian female population aged 15-44 in financial year 2011/2012 as projected by the Australian Bureau of Statistics [ABS];
* Literature on proportion of overall TOPs conducted where gestational age ≤ 49 days

The submission estimated that the rate of TOPs in Australian women was approximately 17.6 per 1,000 women aged between 15 and 44 years and this rate had been relatively constant over the last 5 years. On this basis, the rate of 17.6 TOPs per 1,000 women aged 15-44 years was projected over the next five financial years. As there was some uncertainty around the rate of TOPs in Australian women, highest and lowest plausible rates of TOP in Australia (20 and 15 TOPs per 1,000 women aged between 15 and 44 years) were applied to estimate upper and lower estimates around a mid-point estimate for number of TOPs in Australia. The proportion of TOPs conducted in women with a first-trimester pregnancy was estimated, from the South Australian Abortion Reporting Committee’s 8th annual report,[[6]](#footnote-6) to be approximately 90%.

The submission stated that the proportion of TOPs undertaken by the surgical and medical methods was derived considering that over the six years that mifepristone had been available under the Authorised Prescriber program, the proportion of TOPs undertaken by the medical method had grown to 14%. It was estimated (on the basis of current rates of growth of the MTOP market share) that, in the absence of a PBS listing for mifepristone and misoprostol, the proportion of TOPs that would be likely to be undertaken by the medical method would increase to 20% by year 3 of marketing but would be unlikely to increase further due to significant price barriers to the patient.

Table 2: Projected numbers of TOPs at ≤49 days’ gestation by method of TOP

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **2012/2013** | **2013/2014** | **2014/2015** | **2015/2016** | **2016/2017** |
| Projections of Australian female population aged 15-44 years | 4,726,639 | 4,769,509 | 4,810,548 | 4,841,046 | 4,871,671 |
| Rate of TOP in women aged 15-44 years | 1.76% (1.5% -2.0%) | | | | |
| Estimate of women having TOP per year | 83,189 | 83,943 | 84,666 | 85,202 | 85,741 |
| Proportion of TOPs by medical method | 25% | 30% | 35% | 40% | 45% |
| Estimate of MTOP | 20,797 | 25,183 | 29,633 | 34,081 | 38,584 |
| Estimate of STOP | 62,392 | 58,760 | 55,033 | 51,121 | 47,158 |
| Number of women seeking first trimester TOP | | | | | |
| Rate of first trimester TOP in women aged 15-44 years | 90% (85% - 95%) | | | | |
| Number of first trimester TOP | 74,870 | 75,549 | 76,199 | 76,682 | 77,167 |
| Estimate of MTOP | 18,717 | 22,665 | 26,670 | 30,673 | 34,725 |
| Estimate of STOP | 56,152 | 52,884 | 49,529 | 46,009 | 42,442 |
| Number of women seeking TOP at <50 days’ gestation each year | | | | | |
| Proportion of first trimester TOPs at ≤49 days’ gestation | 85% (75% - 95%) | | | | |
| TOPs at ≤49 days’ gestation | 63,639 | 64,217 | 64,769 | 65,180 | 65,592 |
| Estimate of MTOP | 15,910 | 19,265 | 22,669 | 26,072 | 29,516 |
| Estimate of STOP | 47,730 | 44,952 | 42,100 | 39,108 | 36,076 |

Source: Submission to the March 2013 PBAC meeting and ‘Economic and financial analyses - mifepristone + misoprostol - November 2012 PBAC submission.xls’. Note that the submission provided mid-point estimates and upper and lower estimates which are shown in brackets.

## Previous reviews by the DUSC

When providing advice to the PBAC on the submission seeking listing of mifepristone and misoprostol on the PBS, the DUSC considered the expected utilisation of mifepristone and misoprostol presented in the submission to be a reasonable estimate based on best available sources of data.

DUSC has not previously reviewed the actual PBS utilisation of mifepristone and misoprostol.

# Methods

### Available data

Data of the number of TOPs in Australia came from various sources. Data are presented in financial years (rather than PBS listing years) to align data from these sources.

##### **MTOPs**

Data of the number of MTOPs was based on PBS claims of mifepristone and misoprostol sourced from the Department of Human Services (DHS) Medicare date of supply data using PBS item codes 2672P, 2710P and 10211K.

As this analysis uses date of supply prescription data, there may be small differences compared with publicly available Department of Human Services (DHS) Medicare date of processing data.[[7]](#footnote-7) The publicly available DHS Medicare data only includes subsidised R/PBS prescriptions with prescriptions under the patient co-payment not included. The DHS Medicare data used in this report includes under co-payment prescriptions.

##### **STOPs in private sector**

Data of the number of STOPs in the private sector was sourced from publicly available DHS Medicare statistics for item 35643 available from http://medicarestatistics.humanservices.gov.au/statistics/mbs\_item.jsp.

**STOPs in public sector**

Data of the number of STOPs in the public sector was sourced from Activity Based Funding (ABF) Cost Weights that were used to fund the public hospitals. Up to June 2012 these were available from the Department of Health website. From 1 July 2012 these were sourced from the Independent Hospital Pricing Authority (IHPA). The Cost Weights detail the number of hospital separations for each Australian Refined Diagnosis Related Group (AR-DRG). The number of STOPs in the public sector was determined by DRG code O05Z (Abortion with OR Procedure).

# Results

## Analysis of utilisation

##### **MTOPs**

The number of MTOPs was estimated from PBS utilisation data using the number of mifepristone prescriptions (as misoprostol appears in the data as an additional prescription) and the number of composite packs supplied per financial year.

Table 3: Number of PBS prescriptions of mifepristone (plain or composite pack)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Financial Year** | | |
| **Month** | **2013/2014** | **2014/2015** | **2015/2016** |
| Jul |  | 673 | 1,007 |
| Aug | 238 | 695 | 1,005 |
| Sep | 378 | 716 | 953 |
| Oct | 401 | 681 | 1,092 |
| Nov | 476 | 613 | 1,019 |
| Dec | 507 | 669 | 993 |
| Jan | 448 | 666 | 1,030 |
| Feb | 480 | 715 | 1,110 |
| Mar | 577 | 843 | 1,074 |
| Apr | 481 | 806 | 1,119 |
| May | 709 | 894 | 1,216 |
| Jun | 635 | 950 | 1,236 |
| **Financial Year Total** | **5,330** | **8,921** | **12,854** |

Source: DHS Prescription supply data. Extracted 30 August 2016.

Table 3 shows that use of PBS subsidised mifepristone has increased gradually since listing.

Some women may choose to have mifepristone and misoprostol dispensed on private prescription rather than through the PBS and this use is not captured in the DHS prescription data.

Prior to the listing of the mifepristone and misoprostol co-pack, the misoprostol component (GyMiso) was available with a maximum quantity of 4 x 200 microgram tablets with one repeat. The repeat prescription was intended for dispensing after 1-7 days if termination of pregnancy had not occurred after the first dose. For all MTOPs commenced between 1 August 2013 and 31 January 2015, a subsequent supply of misoprostol was dispensed on less than 2% of occasions (data not shown).

**STOPs in private sector**

Data of the number of STOPs in the private sector was sourced from publicly available DHS Medicare statistics data, per financial year, using MBS code 35643. This code may overestimate the number of STOPs performed, as a proportion of claims are for procedures other than TOP, for example, management of incomplete spontaneous miscarriage. Consistent with the assumption in the submission, 75% of the claims for MBS item 35643 are estimated to be for TOP.

Table 4: Estimated number of STOPs in the private sector based on 75% of services for MBS item 35643.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Financial Year** | | | | | | | | |
| **Month** | **2007/ 2008** | **2008/ 2009** | **2009/ 2010** | **2010/ 2011** | **2011/ 2012** | **2012/ 2013** | **2013/ 2014** | **2014/**  **2015** | **2015/ 2016** |
| Jul | 5,919 | 5,977 | 6,341 | 5,813 | 5,258 | 5,329 | 5,623 | 4,839 | 4,877 |
| Aug | 6,512 | 6,054 | 5,795 | 5,719 | 5,876 | 5,664 | 5,318 | 4,590 | 4,619 |
| Sep | 6,178 | 6,070 | 6,133 | 5,488 | 5,221 | 5,074 | 4,959 | 4,837 | 4,560 |
| Oct | 6,297 | 6,546 | 5,981 | 5,219 | 5,191 | 5,138 | 5,459 | 4,933 | 4,555 |
| Nov | 6,164 | 5,718 | 5,727 | 5,534 | 5,201 | 5,182 | 4,731 | 4,485 | 4,409 |
| Dec | 5,280 | 5,828 | 5,567 | 5,005 | 4,902 | 4,668 | 4,508 | 4,583 | 4,060 |
| Jan | 6,518 | 6,340 | 5,644 | 4,973 | 5,404 | 5,296 | 5,283 | 4,939 | 4,353 |
| Feb | 6,289 | 5,972 | 5,528 | 5,350 | 5,405 | 4,896 | 4,959 | 4,579 | 4,358 |
| Mar | 4,901 | 6,425 | 5,998 | 5,415 | 5,119 | 4,502 | 4,533 | 4,557 | 4,290 |
| Apr | 6,019 | 5,572 | 4,754 | 4,340 | 4,525 | 4,719 | 4,212 | 3,987 | 3,876 |
| May | 6,124 | 6,035 | 5,590 | 5,131 | 5,302 | 5,170 | 4,940 | 4,410 | 3,924 |
| Jun | 5,756 | 5,666 | 5,199 | 5,273 | 4,783 | 4,607 | 4,477 | 4,437 | 3,748 |
| Financial Year Total | 71,957 | 72,203 | 68,257 | 63,260 | 62,187 | 60,245 | 59,002 | 55,176 | 51,629 |
| Estimated number of STOPs (75%) | 53,968 | 54,152 | 51,193 | 47,445 | 46,640 | 45,184 | 44,252 | 41,382 | 38,722 |

##### Source: DHS Medicare data. Extracted 30 August 2016.

**STOPs in public sector**

Data of the number of STOPs in the public sector was sourced from Activity Based Funding (ABF) Cost Weights with details of hospital separations of DRG code O05Z (Abortion with OR Procedure).

Table 5: Estimated number of STOPs in the public sector based on hospital separation statistics.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Financial year** | **2007/ 2008** | **2008/ 2009** | **2009/ 2010** | **2010/ 2011** | **2011/ 2012** | **2012/ 2013** | **2013/ 2014** |
| Number of separations | 26,670 | 29,172 | 28,349 | 26,318 | 25,914 | 25,484 | 25,300 |

Source: Department of Health and Independent Hospital Pricing Authority

At the time this analysis was conducted, the most recent data of the number of STOPs in the public setting was available to the financial year ending June 2014. An extrapolation of these data to estimate STOPs in 2014/15 and 2015/16 was not undertaken as it was expected that the number of STOPS would have declined as a result of the PBS listing of mifepristone.

The decrease in the number of public and private sector STOPs in the 2010/2011 and 2011/2012 financial years was likely due to mifepristone and misoprostol being supplied through the TGA’s Authorised Prescriber program before mifepristone was registered on the ARTG on 29 August 2012 .

## Analysis of actual versus predicted utilisation

The submission estimated that without a PBS listing for mifepristone and misoprostol between 14% and 20% of TOPs would be MTOPs. With a PBS listing, the proportion of TOPs by medical method would be 25% in year 1, increasing to 45% in year 5. Predicted and actual use is presented in Table 6.

Table 6: Predicted numbers of TOPs compared to actual

|  |  |  |  |
| --- | --- | --- | --- |
|  | **2013/2014** | **2014/2015** | **2015/2016** |
| **Number of TOPs** | | | |
| Predicted midpoint estimate (predicted plausible range) | 83,943  (71,543 – 95,390) | 84,666  (72,158 – 96,211) | 85,202  (72,616 – 96,821) |
| Actual | 74,882 | N/A | N/A |
| Difference | − 9,061 | N/A | N/A |
| **Number of MTOPs** | | | |
| Predicted <50 days’ gestation | 19,265 | 22,669 | 26,072 |
| Predicted first trimester | 22,665 | 26,670 | 30,673 |
| Predicted estimate for comparisona | 19,265 | 24,336 | 30,673 |
| Actual | 5,330 | 8,921 | 12,854 |
| Difference | − 13,935 | − 15,415 | − 17,819 |
| **Number of STOPs** | | | |
| Predicted total STOPs | 58,760 | 55,033 | 51,121 |
| Actual STOPs | 69,552 | N/A | N/A |
| Private STOPs | 44,252 | 41,382 | 38,722 |
| Public STOPs | 25,300 | N/A | N/A |
| Difference | 10,792 | N/A | N/A |

Source: predicted use for financial years from submission to March 2013 PBAC.

a1 August 2013 to 31 January 2015 the listing was for up to 49 days’ gestation. From 1 February 2015 the listing was for up to 63 days’ gestation

N/A = data on public sector STOPs and therefore total STOPs not yet available for 2014/15 and 2015/16

The number of MTOPs using mifepristone/misoprostol supplied through the PBS has been less than half of that expected. This may be due to a range of factors including that fewer women are electing the medical method than anticipated[[8]](#footnote-8), that some mifepristone and misoprostol may be provided on private prescription and not captured in PBS data, or that there are barriers to use including jurisdictional laws[[9]](#footnote-9),[[10]](#footnote-10) or the number of registered prescribers. A recent media article stated that only 1,244 doctors have become certified prescribers.[[11]](#footnote-11) Between 1 August 2013 and 30 June 2016, 495 prescribers wrote at least one prescription for mifepristone that was supplied through the PBS.

The 2013/14 data indicate that the introduction of mifepristone and misoprostol on the PBS has not increased the number of TOPs in Australia per year. In 2013/14 the number of TOPs, estimated from all available data sources, was 74,882 (15.58 per 1000 women aged 15-44 years[[12]](#footnote-12)). This was lower than predicted and well within the upper and lower plausible range estimated in the submission. It is important to note that this number will underestimate MTOPs with gestation age 50-62 days which was not PBS subsidised in 2013/14 and may have been supplied privately in some cases. The submission’s estimates, presented in Table 2, show that in 2013/2014 this may be about 3,400 patients; but given the low uptake of the medical method the number of patients is likely to be much lower than this. In addition, MTOPs conducted after 63 days of gestation will be underestimated with available data as this use is not PBS subsidised. This is likely to be a small component based on 2012 data from the South Australian Abortion Reporting Committee report[[13]](#footnote-13) that indicated that 2.8% of mifepristone and misoprostol was for second trimester terminations.

A comparison of predicted and actual TOPs for 2014/15 and 2015/16 cannot be completed at this stage because data on public sector STOPs is not yet available. Other data sources that could be used to supplement the PBS, private and public hospital data, such as the South Australian Abortion Reporting Committee Report, are also not yet available for this time period. However, the decline in the number of STOPS in the private sector in 2014/15 and 2015/16 does suggest that MTOP is providing an alternative to STOP rather than increasing the number of TOPs.

# DUSC consideration

DUSC acknowledged the responses to the report from the sponsor MS Health, and from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and the Royal Australian College of General Practitioners (RACGP) which assisted in understanding the reasons why the proportion of TOPs undertaken by the medical method has been lower than expected. Possible reasons identified in the report were confirmed in the stakeholder responses, including that fewer women are choosing the method, jurisdictional laws in some states pose a barrier, there are a low number of certified prescribers, the requirement (pre-2015) by some insurers for general practitioners to have procedural medical indemnity insurance, and that there is some private prescribing not captured in the PBS dataset. The sponsor provided additional data to assist in quantifying private prescribing. '''' ''''' ''''''''''''' ''''''''''''' '''''''''''' '''' '''''' ''''''''''''''''''''''' ''''' ''''''''''''''''''''''' ''''''' ''''' ''''''''''''''' ''''''''''''''''''''''' '''''''''''''' '''' '''''''''''''''''''''''' ''''''''''''''''' '''''''''''' '''''' '''''''''''' ''''' '''''' '''''''''''''' '''''''' ''''''''''''''''''' ''''''' '''''''''''''' ''''' ''' ''''''' ''''''''''' However, the sponsor and DUSC recognised that it is not known to what extent private prescribing is due to patients being ineligible to receive medicines under the PBS (e.g. overseas visitors), patient choice, or due to other reasons.

Additional reasons identified in the responses that may contribute to the lower than expected use of the medical method for termination include the potential for low awareness of the availability of this option; there are limited support services and limited access to STOPs in the event of a failed MTOP in some areas of Australia; that despite procedural medical indemnity insurance no longer being required, GPs may not have revisited their original decision not to offer MTOP or that medical defence organisations require GPs to have particular support requirements in place to manage adverse events; that there is no specific MBS item for medical termination services; and that MTOP may not be offered on commercial grounds.

DUSC considered that the barriers to use were not sufficiently understood and factored into the estimated use at the time of listing on the PBS. DUSC considered that while utilisation of the medical methods is slowly increasing, predicted levels are unlikely to be reached in the next few years. DUSC also noted the stakeholder responses indicated that the proportion of TOPs by the medical method may grow in the next few years if barriers to use are addressed including awareness, education, access and law reform. The establishment of clinical care pathways designed via local Primary Health Networks (PHNs) was identified by the RACGP as a factor that may encourage GPs to become certified prescribers.

# DUSC actions

The DUSC requested that the report be provided to the PBAC.

# Context for analysis

The DUSC is a Sub Committee of the Pharmaceutical Benefits Advisory Committee (PBAC). The DUSC assesses estimates on projected usage and financial cost of medicines.

The DUSC also analyses data on actual use of medicines, including the utilisation of PBS listed medicines, and provides advice to the PBAC on these matters. This may include outlining how the current utilisation of PBS medicines compares with the use as recommended by the PBAC.

The DUSC operates in accordance with the quality use of medicines objective of the National Medicines Policy and considers that the DUSC utilisation analyses will assist consumers and health professionals to better understand the costs, benefits and risks of medicines.

The utilisation analysis report was provided to the pharmaceutical sponsors of each drug and comments on the report were provided to DUSC prior to its consideration of the analysis.

# Sponsors’ comments

MS Health Pty Ltd: The sponsor has no comment.

# Disclaimer

The information provided in this report does not constitute medical advice and is not intended to take the place of professional medical advice or care. It is not intended to define what constitutes reasonable, appropriate or best care for any individual for any given health issue. The information should not be used as a substitute for the judgement and skill of a medical practitioner.

The Department of Health (DoH) has made all reasonable efforts to ensure that information provided in this report is accurate. The information provided in this report was up-to-date when it was considered by the Drug Utilisation Sub-committee of the Pharmaceutical Benefits Advisory Committee. The context for that information may have changed since publication.

To the extent provided by law, DoH makes no warranties or representations as to accuracy or completeness of information contained in this report.

To the fullest extent permitted by law, neither the DoH nor any DoH employee is liable for any liability, loss, claim, damage, expense, injury or personal injury (including death), whether direct or indirect (including consequential loss and loss of profits) and however incurred (including in tort), caused or contributed to by any person’s use or misuse of the information available from this report or contained on any third party website referred to in this report.

1. MS-2 Step (mifepristone) Australian approved consumer medicine information. Carlton VIC: MS Health. Leaflet prepared December 2014. <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2015-CMI-01028-1&d=2016070516114622483> [↑](#footnote-ref-1)
2. Mifepristone Linepharma (mifepristone) Australian approved product information. Carlton VIC: MS Health. Date of most recent amendment 12 May 2015. <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2012-PI-02513-1&d=2016083116114622483> [↑](#footnote-ref-2)
3. Australian Medicines Handbook. 2016 pp 504-505. [↑](#footnote-ref-3)
4. Pratt et al. How many abortions are there in Australia? A discussion of abortion statistics, their limitations, and options for improved statistical collection. Parliamentary Research Brief. 14 February 2005, no. 9, 2004–05, ISSN 1832-2883 [↑](#footnote-ref-4)
5. Answers to Questions on notice Senate Community Affairs Committee Budget Estimates 2012-2013, 30 & 31 May and 1 June 2012. Question: E 12-068 [↑](#footnote-ref-5)
6. South Australian Abortion Reporting Committee, Eighth Annual Report - For the Year 2010. February 2012 [↑](#footnote-ref-6)
7. PBS statistics. Australian Government Department of Human Services Medicare. Canberra. Available from <<http://www.medicareaustralia.gov.au/provider/pbs/stats.jsp>>. [↑](#footnote-ref-7)
8. How do women seeking abortion choose between surgical and medical abortion? Perspectives from abortion service providers; Newton, D, Bayly, C, McNamee, K, Hardiman, A, Bismark, M, Webster, A, Keogh, L; Australian and New Zealand Journal of Obstetrics and Gynaecology 2016 [↑](#footnote-ref-8)
9. Abortion law in Australia: it’s time for national consistency and decriminalisation; de Costa C, Douglas H; Medical Journal of Australia; 2015; 203 (9): 349-350. [↑](#footnote-ref-9)
10. Abortion law across Australia – A review of nine jurisdictions; de Costa C, Douglas H, Hamblin J, Ramsay P, Shircore M; Australian and New Zealand Journal of Obstetrics and Gynaecology 2015 [↑](#footnote-ref-10)
11. Doctors call for more GPs to provide abortion drug RU486; The Age; 27 August 2016; <http://www.theage.com.au/victoria/doctors-call-for-more-gps-to-provide-abortion-drug-ru486-20160827-gr2kwh.html> [↑](#footnote-ref-11)
12. Australian Bureau of Statistics; Table B9. Population projections, By age and sex, Australia - Series B; June 2013 [↑](#footnote-ref-12)
13. Annual report of the South Australian Abortion Reporting Committee Tenth Annual Report - For the Year 2012; July 2014 [↑](#footnote-ref-13)