6.04 HUMAN MENOPAUSAL GONADOTROPHIN, multidose injection, 600 IU, Menopur®, Ferring Pharmaceuticals Pty Ltd.

1 Purpose of Application

1.1 The submission requested a Section 85, Restricted Benefit listing for highly purified human-menopausal-gonadotrophin (HP-hMG) for treatment of anovulatory infertility.

2 Requested listing

2.1 The requested listing is shown below.

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
GONADOTROPHIN- MENOPAUSAL HUMAN (HMG) gonadotrophin-menopausal human 600 international units injection [1 x 600 international units vial] & inert substance diluent [1 x 1mL syringes], 1 pack	3	0	$[redacted]	Menopur Ferring

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	☒Medical Practitioners
Condition:	Anovulatory infertility
PBS Indication:	Anovulatory infertility
Treatment phase:	-
Restriction Level / Method:	☒Restricted benefit ☐Authority Required - In Writing ☐Authority Required - Telephone ☐Authority Required – Emergency ☐Authority Required - Electronic ☐Streamlined
Administrative Advice	Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived. Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception. Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment. Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

2.2 Listing was requested on a cost-minimisation basis against follitropin alfa for the same indication.

3 Background

3.1 HP-hMG was TGA registered in July 2011 for women with anovulatory infertility, and controlled ovarian hyperstimulation (COH) as part of an Assisted Reproductive Technology (ART) treatment program.

3.2 HP-hMG has not been previously considered by the PBAC for the anovulatory infertility indication. At the March 2012 meeting, the PBAC recommended the listing of HP-hMG as an Authority required item under the Section 100 IVF program for use as part of ART. Listing was on a cost-minimisation basis against follitropin alfa. The equi-effective doses were 1.01 IU of HP-hMG and 1 IU follitropin alfa.

3.3 Two gonadotrophins are listed under Section 85 for patients with anovulatory infertility, follitropin alfa and follitropin beta. The PBAC has previously accepted that follitropin beta is equivalent to follitropin alfa on a per unit basis.

3.4 The requested PBS listing is consistent with the TGA registered indication, and is the same as for the gonadotrophins currently available on the PBS for patients with anovulatory infertility (follitropin alfa and follitropin beta).

4 Clinical place for the proposed therapy

4.1 Gonadotrophins are used as a second-line treatment for ovulation induction in women who do not ovulate or conceive on clomiphene citrate. Follitropin alfa and follitropin beta are follicle stimulating hormones (FSH) and are used to assist follicular growth and ovulation.

4.2 HP-hMG is proposed as an alternative gonadotrophin.

5 Comparator

5.1 The submission nominated follitropin alfa as the main comparator.

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

6 Consideration of the evidence

Sponsor hearing

6.1 There was no hearing for this item.

Consumer comments

6.2 The PBAC noted that no consumer comments were received for this item.

Clinical trials

6.3 The submission was based on one head-to-head trial comparing HP-hMG to follitropin alfa (N=184).

6.4 Details of the trial presented in the submission are provided in the table below.

Table 1: Trials and associated reports presented in the submission

Trial ID/First Author	Protocol title/ Publication title	Publication citation
Direct randomised trial		
CS002	FE999906 CS002 A Randomized, Open-label, Assessor-blind, Parallel Group, Multi-Center, Non-inferiority Study Comparing Highly Purified Menotrophin (MENOPUR) SC and Recombinant FSH (GONAL-F) SC for Ovulation Induction Using a Chronic Low-dose Step-up Protocol in Women with WHO Group II Anovulatory Infertility Failing to Ovulate or Conceive on Clomiphene Citrate	Ferring Pharmaceuticals. Internal study report. 23 Feb 2005
	Platteau P. Similar ovulation rates, but different follicular development with highly purified menotrophin compared with recombinant FSH in WHO Group II anovulatory infertility: a randomised controlled study.	Human Reproduction. 2006; 21 (7): 1798-1804.
	Arce JC & Smitz J: Exogenous hCG activity, but not endogenous LH activity, is positively associated with live birth rates in anovulatory infertility.	Human Fertility. 2011; 14(3): 192-199.
	Platteau P. Ovulation rate with a highly purified menotrophin and a recombinant FSH in women unresponsive to clomiphene citrate.	Fertility and Sterility. 2005; 84 (Suppl 1): S324-325.

Source: Table B-3 p 18 of the submission.

6.5 The key features of the direct randomised trial are summarised in the table below.

Table 2: Key features of the included evidence

Trial	N	Design/ duration	Risk of bias	Patient population	Outcomes
HP-hMG vs follitropin alfa					
CS002	184	R, OL, Assessor blind, MC All pregnancies were followed up until live birth (delivery).	Low	Females with anovulatory infertility	Ovulation rate, ongoing pregnancy, live birth rate

Source: compiled during the evaluation
MC=multi-centre; OL=open label; R=randomised.

6.6 Although the overall risk of bias in CS002 was low, there were some differences in the baseline characteristics across the treatment groups, which suggest the trial sample size calculation may have been slightly under-powered, at least with regards to the subset of key prognostic correlates. A higher percentage of patients in the HP-hMG group had a BMI ≥ 30 kg/m^2 (33% vs 15%), failed to ovulate on clomiphene citrate (54% vs 38%), and the primary reason for infertility being polycystic ovaries (71% vs 59%). The ESC noted that the primary analysis was not adjusted for differences in these baseline patient characteristics. Whilst an adjusted ITT analysis observed comparable effects after adjusting for BMI and age via inclusion as fixed

effects in the regression model, this additional analysis was not further adjusted for differences in failure to ovulate on prior clomiphene citrate and the primary reason for infertility.

Comparative effectiveness

6.7 A summary of the comparative effectiveness for HP-hMG versus follitropin alfa is presented in Table 3 and Table 4.

6.8 For the ITT analysis, the mean difference in the ovulation rate for HP-hMG and follitropin alfa was -1.43% (95% CI: -12.0, 9.1). Based on the non-inferiority limit of -20%, the submission claimed that HP-hMG is non-inferior to follitropin alfa. The PSCR (p.1) claimed a 20% reduction in ovulation rate is expected to translate to a 5% decrease in live birth rate, and argued that a 5% decrease was considered by the trial designers to be a clinically important difference between the treatments.

6.9 The results of the PP analysis were consistent with the ITT analysis. Whilst the primary analysis was not adjusted for the various imbalance in baseline characteristics by trial arm, a sensitivity analysis of the ITT population (using a logistic regression adjusting for age and continuous BMI only) was generally consistent with the primary unadjusted ITT results, although this adjusted ITT did not control for baseline differences in failure to ovulate on first-line clomiphene citrate and primary reason for infertility. The Pre-PBAC Response (p.1) clarified that "the analysis of the primary outcome included a prospectively planned sensitivity analysis of efficacy that was adjusted for age and BMI, because these variables were known to have a potential effect on ovulation rate, and not because an imbalance in any of these variables was expected in the study groups."

6.10 All ongoing pregnancies resulted in live births. The mean difference in the proportion of patients with a live birth for HP-hMG and follitropin alfa was 2.92% (95% CI -13.4%, 7.59%). The submission did not nominate a non-inferiority margin for the outcomes of live births or ongoing pregnancy. However, the lower 95% confidence limit exceeds the 10% non-inferiority margin previously accepted by the PBAC.

Table 3: Results of the primary outcome across the direct randomised trial

	HP-hMG n with event/N (%)	Follitropin alfa n with event/N (%)	Mean difference (95% CI)*
Primary outcome: Ovulation rate			
PP	60/70 (85.7)	71/83 (85.5)	0.17 (-11.0, 11.33)
ITT	76/91 (83.5)	79/93 (84.9)	-1.43 (-12.0, 9.10)

Source: Table B-17, Table B-18 p48, of the submission; CS002 CSR Table 9-1 p73, Table 9-9 p81.
Abbreviations: CI = confidence interval; HP-hMG = highly purified human menopausal gonadotrophin; ITT = intention-to-treat; PP = per protocol. * *Pre-specified non-inferiority limit = -20%*

Table 4: Results of the patient-relevant outcome across the direct randomised trial

	HP-hMG n with event/N (%)	Follitropin alfa n with event/N (%)	Mean difference (95% CI)*
Secondary outcomes			
Ongoing pregnancy (PP)	13/70 (18.6)	14/83 (16.9)	1.70% (-10.5%, 13.9%)
Ongoing pregnancy (ITT)	13/91 (14.3)	16/93 (17.2)	-2.92% (-13.4%, 7.59%)
Live births (ITT)	13/91 (14.3)	16/93 (17.2)[a]	-2.92% (-13.4%, 7.59%)

Source: Table B-19 p50, text p51 of the submission; CS002 CSR Table 9-1 p73, Table 9-9 p81.
Abbreviations: CI = confidence interval; HP-hMG = highly purified human menopausal gonadotrophin; ITT = intention-to-treat; PP = per protocol.
[a] The CSR report Table 11-3 p116 there were 18 live-born children in the follitropin alfa group. Two subjects in the trial had multiple pregnancies which resulted in twins. There were no twin pregnancies in the HP-hMG group.
** A non-inferiority limit was NOT nominated for either, 10% margin previously accepted by PBAC*

6.11 The PSCR (p.1) stated that the trial was not powered to determine a difference between the study groups on the outcome of live births. The PSCR also stated that against the main comparator, the outer limits of -10.5% (PP population; live birth rate and ongoing pregnancy rate) and -13.4% (ITT population; ongoing pregnancy rate) for the lower 95% confidence limit were reasonable and consistent with results on for comparisons on other clinically relevant and adequately powered outcomes.

Comparative harms

6.12 The comparison of safety outcomes for HP-hMG and follitropin alfa were based on the direct randomised trial. The proportion of patients experiencing AEs was similar for the two treatment groups (HP-hMG 41% vs follitropin alfa 40%). In both arms 22% of patients experienced an AE that was likely to be related to study treatment. OHSS was reported for four subjects; one in the HP-hMG group (mild grade 1) and three in the follitropin alfa group (one each of mild grade 1, mild grade 2, and moderate grade 3).

6.13 Amongst the infants born after delivery, there was one SAE in the HP-hMG group (meconium in amniotic fluid) and three in the follitropin alfa group (fetal distress syndrome, premature labour, infection) that resulted in admission of the infant to a neonatal unit. All infants recovered.

Benefits/harms

6.14 A summary of the comparative benefits and harms for HP-hMG versus follitropin alfa is presented in the table below.

Table 5: Summary of comparative benefits and harms for HP-hMG and follitropin alfa

	HP-hMG	Follitropin alfa	RR (95% CI)	Event rate/100 patients*		RD (95% CI)
				HP-hMG	Follitropin alfa	
Benefits						
Ovulation rate						
ITT	76/91	79/93	0.98 (0.87, 1.11)	83.5	84.9	-1.43% (-12.0%, 9.1%)
Ongoing pregnancy						
ITT	13/91	16/93	0.83 (0.42, 1.63)	14.3	17.2	-2.92% (-13.4%, 7.59%).
Live births						
ITT	13/91	16/93	0.83 (0.42, 1.63)	14.3	17.2	-2.92% (-13.4%, 7.59%).
Harms						
	HP-hMG	**Follitropin alfa**	**RR (95% CI)**	**Event rate/100 patients***		**RD (95% CI)**
				HP-hMG	**Follitropin alfa**	
All causality AEs						
Safety population	38/92	37/92	1.03 (0.72, 1.46)	41.3	40.2	1.1% (-13.1%, 15.3%)
Mild OHSS (Grade 1 and 2)						
Safety population	1/92	2/92	0.50 (0.05, 5.42)	1.1	2.2	-1.1% (-4.7%, 2.6%)
Moderate OHSS (Grade 3)						
Safety population	0	1/92	-	0	1.1	-1.1% (-3.2%, 1.0%)

Source: Table B-17 p48, Table B-19 p50, text p51, Table B-20 p52, Table B-23 p54 of the submission; text in italics were compiled during the evaluation

Abbreviations: AE = adverse event; CI = confidence interval; HP-hMG = highly purified human menopausal gonadotrophin; ITT = intention-to-treat; OHSS = ovarian hyperstimulation syndrome; PP = per protocol; RD = risk difference; RR = risk ratio.

* Event rate is based on one cycle of treatment.

* Non-inferiority limit = -20% for ovulation rate. No limit nominated for either ongoing pregnancy or live births. A 10% non-inferiority margin has been previously accepted by the PBAC for ongoing pregnancy and live birth rates.

Clinical claim

6.15 The submission described HP-hMG as non-inferior in terms of comparative effectiveness and non-inferior in terms of comparative safety over the primary comparator, follitropin alfa.

6.16 The claim may be reasonable for the ovulation rate, but not for the more clinically and patient relevant outcomes of ongoing pregnancy and live birth rate. The safety of HP-hMG and follitropin alfa appears similar.

6.17 The ESC considered that the submission's clinical claim of non-inferior comparative effectiveness over follitropin alfa may be reasonable for the outcome of ovulation rate, but may not adequately supported for the outcome of ongoing pregnancy if using a -10% non-inferiority limit as previously accepted by the PBAC for the secondary outcomes.

6.18 The ESC considered that the comparative harms were likely to be similar between HP-hMG and follitropin alfa, and that a claim of non-inferior comparative safety may be reasonable.

6.19 The PBAC considered that the claim of non-inferior comparative effectiveness was not adequately supported by the data.

6.20 The PBAC considered that the claim of non-inferior comparative safety was reasonable.

Economic analysis

6.21 The equi-effective doses are estimated in the submission as 1 IU of HP-hMG and 1 IU of follitropin alfa over a treatment cycle based on CS002.

6.22 Although there were no statistically significant differences in terms of duration, total dose or threshold dose, there was a tendency towards a longer duration of treatment, higher total dose, and higher threshold dose in the HP-hMG group compared with the follitropin alfa group (see Table 6).

6.23 The higher doses used in the HP-hMG group may be, at least in part, due to HP-hMG group including patients with a statistically significantly higher average BMI, more patients who previously failed to ovulate on clomiphene citrate, and more patients with primary infertility due to polycystic ovaries. However, even after adjusting for these differences in a multivariate analysis, a higher proportion of patients treated with HP-hMG required a threshold dose greater than 75 IU.

Table 6: Summary of dose administration in the trial

	HP-hMG (N=91)	Follitropin alfa (N=93)
Treatment days		
Mean (SD)	15.3 (7.9)	12.0 (5.0)
Median (range)	13 (7-42)	11 (1-28)
Total dose (IU)		
Mean (SD)	1491 (1177)	1022 (580)
Median (range)	1088 (525-6338)	825 (75-2963)
Threshold dose[a], n (%)	83 (100%)	82 (100%)
75 IU	44 (53%)	61 (74%)
112.5 IU	28 (34%)	17 (21%)
150 IU	6 (7%)	4 (5%)
187.5 IU	5 (6%)	-

Source: submission Table B-12 p34

Abbreviations: hCG = human chorionic gonadotrophin; HP-hMG = highly purified human menopausal gonadotrophin; SD = standard deviation

[a] Only applicable, if the hCG criteria are met

6.24 The equi-effective doses of HP-hMG and follitropin alfa for the ART indication were based on the weighted average doses reported in the six key trials included in the ART submission. Using the same approach for the anovulatory infertility indication, the equi-effective doses would be HP-hMG 1.46 IU (1491 / 1022) and follitropin alfa 1.00 IU, based on the mean trial doses.

6.25 The PSCR (p.1-2) disputed the evaluator's proposal that the equi-effective dose ratio should be HP-hMG 1.46 IU and follitropin alfa 1.00 IU. The PSCR argued that the higher doses used in the HP-hMG group may be at least in part due to differences in major baseline characteristics at entry.

Table 7: Summary statistics of total gonadotrophin dose

Summary statistic	Total gonadotrophin dose		
	HP-hMG (IU)	rFSH (IU)	Ratio
Mean ITT	1491	1022	1.46
Median ITT	1088	825	1.32
Mean PP	1390	981	1.42
Median PP	938	825	1.14

Source: Gonadotrophin Pre-Sub-Committee Response, p.2

6.26 The ESC agreed with the PSCR that the distribution of doses used was skewed, however considered that it was appropriate to use the median ITT doses to determine the equi-effective doses. The ESC considered that using the median ITT doses, the equi-effective doses would be HP-hMG 1.32 IU and follitropin alfa 1.00 IU.

6.27 The requested price for HP-hMG 600 IU (AEMP $[redacted] per pack) is the same as the current price for HP-hMG for the ART indication. HP-hMG was listed at a lower price per IU compared with follitropin alfa for the ART indication to reflect the dose relativity of 1.01:1 and additional wastage. The overall price reduction was [redacted]% and hence HP-hMG was listed with an AEMP of $[redacted] per IU compared with an AEMP of $[redacted] per IU for follitropin alfa.

6.28 The proposed price for HP-hMG and the current prices for follitropin alfa are presented in Table 8. The revised price calculated using the equi-effective doses from the median doses in CS002 to estimate the equi-effective doses are also presented in Table 8.

6.29 As for the ART indication, there may be additional wastage with HP-hMG for the anovulatory infertility indication due to the availability of only one strength (600 IU) compared with three strengths for follitropin alfa (300 IU, 450 IU and 900 IU).

Table 8: Proposed and revised HP-hMG prices using median trial doses

	AEMP per IU	AEMP per pack	Max Qty	DPMQ
Follitropin alfa 900 IU				
Current price	$[redacted]	$[redacted]	1800	$[redacted]
HP-hMG 600 IU				
Proposed price	$[redacted]	$[redacted]	1800	$[redacted]
Based on equi-effective doses of HP-hMG 1.32 IU and follitropin alfa 1.00 IU	$[redacted] [a]	$[redacted]	1800	$[redacted]
Based on equi-effective doses of HP-hMG 1.32 IU and follitropin alfa 1.00 IU + [redacted]% price reduction	$[redacted] [b]	$[redacted]	1800	$[redacted]

Source: compiled during the evaluation. *Texts in italics were calculated during the evaluation.*
Abbreviations: AEMP = approved ex-manufacturer price; DPMQ = dispensed price for maximum quantity; HP-hMG = highly purified human menopausal gonadotrophin.
[a] $[redacted] / [redacted]
[b] ($[redacted] / [redacted]) x ([redacted])

Drug cost/patient/cycle: $[redacted]

6.30 For patients requiring a total dose of ≤ 1800 IU the dispensed cost of HP-hMG is $[redacted] per patient per cycle and the dispensed cost of follitropin alfa is $[redacted]. A proportion of patients treated with HP-hMG and follitropin alfa would require a second

script. The proportion is likely to be higher with HP-hMG than with follitropin alfa due to the requirement for higher doses. For patients taking follitropin alfa there is also the possibility of providing smaller quantities for the second script (300 or 450 IU compared with 600 IU for HP-hMG).

Estimated PBS usage & financial implications

6.31 This submission was not considered by DUSC. A summary of the estimated use and financial implications for listing HP-hMG on the PBS is presented in Table 9.

Table 9: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5
Estimated extent of use					
Follitropin alfa 900 IU scripts	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
HP-hMG 600 IU market share	2%	6%	18%	30%	33%
HP-hMG 600 IU scripts	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Estimated net cost to PBS/RPBS					
HP-hMG 600 IU	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]
Follitropin alfa 900 IU	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]
Estimated net cost to MBS					
Net cost to MBS	$0	$0	$0	$0	$0
Estimated total net cost					
Net cost to PBS/RPBS/MBS	-$[redacted]	-$[redacted]	-$[redacted]	-$[redacted]	-$[redacted]

Source: Table E-4 p68, Table E-5 p68, Table E-6 p89, Table E-9 and Table E-10 p71 of the submission.
Abbreviations: HP-hMG = highly purified human menopausal gonadotrophin; MBS = Medicare Benefits Schedule; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

The redacted table above shows that at year 5, the estimated number of scripts would be less than 10,000 and the net savings to PBS would be less than $10 million.

6.32 The uptake of HP-hMG does not consider that patients treated with HP-hMG may require higher doses, as observed in the trial data, and that only one presentation is available. Revised estimated financial implications are provided in Table 9 assuming an equi-effective dose ratio as suggested by the ESC, of 1.32:1. These costs do not include the potential for increased wastage with HP-hMG compared with follitropin alfa.

Table 10: Revised estimated financial implications to the PBS assuming equi-effective doses of 1.32:1

	Year 1 2015/16	*Year 2 2016/17*	*Year 3 2017/18*	*Year 4 2018/19*	*Year 5 2019/20*
Net Cost to Government					
HP-hMG 600 IU x 3	*$[redacted]*	*$[redacted]*	*$[redacted]*	*$[redacted]*	*$[redacted]*
Follitropin alfa 900 IU x 2	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]
Net impact	***$[redacted]***	***$[redacted]***	***$[redacted]***	***$[redacted]***	***$[redacted]***

Source: Table E-9 and Table E-10 p71 of the submission; text in italics were compiled during the evaluation.
Abbreviations: HP-hMG = highly purified human menopausal gonadotrophin; PBS = Pharmaceutical Benefits Scheme.

Quality Use of Medicines

6.33 The submission stated activities are in place to support quality use of medicines.

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

7 PBAC Outcome

7.1 The PBAC decided not to recommend that the PBS listing for human menopausal gonadotrophin be extended to include treatment of anovulatory infertility. In making its recommendation, the PBAC considered that the evidence presented in the submission did not adequately support a claim of non-inferiority to the comparator, follitropin alfa. The PBAC further considered that extending the listing of human menopausal gonadotrophin would not address any unmet clinical need.

7.2 The PBAC considered that there was considerable uncertainty regarding the equi-effective doses, noting that the evaluation and the ESC advised different equi-effective dose ratios (1.46:1 and 1.32:1 respectively) to the submission's proposed 1:1 ratio.

7.3 The PBAC considered that the submission's nominated main comparator, follitropin alfa, was appropriate.

7.4 The PBAC noted that the submission was based on a direct trial comparing human menopausal gonadotrophin and follitropin alfa. The PBAC considered that there were some differences in the baseline characteristics across the treatment groups in the key clinical trial CS002, noting that a higher proportion of patients in the human menopausal gonadotrophin group had a BMI ≥ 30 kg/m2, failed to ovulate on clomiphene citrate, and the primary reason for infertility being polycystic ovaries.

7.5 The PBAC noted that the non-inferiority margin of -20% was met for the primary outcome of ovulation rate, however the PBAC considered the confidence interval around the mean difference to be wide (-1.43% (95% CI: -12.0, 9.1)). The PBAC noted that for the patient relevant outcome of live births and ongoing pregnancy, the lower confidence interval exceeded the 10% non-inferiority margin previously accepted by the PBAC. Although it was acknowledged that the trial was not powered to determine a difference between groups for these secondary outcomes, the PBAC considered that it could not confidently accept a claim of non-inferiority based on the results for ovulation rate.

7.6 The PBAC considered that a claim of non-inferior safety of human menopausal gonadotrophin to follitropin alfa may be reasonable, given the similar proportion of patients experiencing adverse events in the two treatment groups in the trial.

7.7 The PBAC noted that the proportion of patients requiring a second prescription was likely to be higher with gonadotrophin compared to follitropin alfa due to the potential requirement for higher doses. There was also potential for more wastage as human menopausal gonadotrophin is only available in one strength while follitropin alfa is available in three strengths. The PBAC considered that due to uncertainty around the clinical claim and equi-effective doses, the financial estimates provided in the submission could not be relied upon.

7.8 The PBAC advised that should the sponsor wish to make a resubmission, in the absence of new clinical data, the sponsor could propose a claim of inferior comparative effectiveness to follitropin alfa and provide appropriately adjusted estimates of cost-effectiveness.

7.9 The PBAC noted that this submission is eligible for an Independent Review.

Outcome:
Rejected

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

9 Sponsor's Comment

Ferring is disappointed with the outcome and will continue to work constructively with the PBAC towards the listing of MENOPUR for patients with anovulatory infertility.