

26 July 2002

To all Suppliers, Medical Groups
and Interested Parties

By facsimile (3 pages)

Consultation on the Schering proposal involving Mirena, Nova-T, Prognova and Nuvelle

PHARMAC has signed a provisional agreement with Schering (NZ) dated 19 July 2002 regarding the listing of Mirena (levonorgestrel intrauterine system) for heavy menstrual bleeding (HMB) and amendments to the terms of listing of the pharmaceuticals Nova-T (intrauterine device), Prognova (oestradiol valerate) and Nuvelle (oestradiol with levonorgestrel).

The main features of the proposal are as follows:

Mirena (levonorgestrel intrauterine system) for heavy menstrual bleeding

1. PHARMAC proposes to list, with effect from 1 October 2002, Mirena (levonorgestrel intrauterine system) under the Other Progestogen Preparations of the Pharmaceutical Schedule at the price and subsidy of \$269.50 per intrauterine system (ex-manufacturer, exclusive of GST).
2. The proposed listing of Mirena would be subject to the following Special Authority criteria:

Special Authority

- a) Mirena is subsidised for use in patients with a clinical diagnosis of heavy menstrual bleeding who have failed to respond to or are unable to tolerate other appropriate pharmaceutical therapies as per the Heavy Menstrual Bleeding Guidelines together with evidence of either i) a serum ferritin level below 16µg/l; or ii) a Haemoglobin level of less than 120g/l.
- b) Reapplications are to be made for subsequent insertions. The criteria for reapplication are:
 - clinical improvement of heavy menstrual bleeding; or
 - removal or expulsion of a previous Mirena insertion for heavy menstrual bleeding within 3 months of that previous insertion.

All reapplications are to state the date when Mirena was previously inserted into the patient.

- c) Applications and reapplications for Special Authority to be made by general practitioners or an appropriate specialist.
- d) Applications and reapplications to be made on a PHARMAC approved form.
- e) Approvals are valid for three months and for one Mirena insertion only.

Note: Levonorgestrel-releasing intra-uterine system is not subsidised for use as a contraceptive.

3. The proposed Special Authority criteria would be subject to review by the Pharmacology and Therapeutics Advisory Committee at its 22 August 2002 meeting.
4. Schering would reimburse PHARMAC the full cost of the subsidy paid in respect of the treatment of Mirena where a practitioner informs Schering and PHARMAC that Mirena has been removed or expelled from a patient within 3 months of insertion.

Nova-T

1. PHARMAC proposes to amend, with effect from 1 October 2002, the terms of listing of Nova-T intrauterine device. The price and subsidy would be \$28.00 per intrauterine device OP (ex-manufacturer, exclusive of GST).
2. PHARMAC proposes to apply reference pricing with effect from 1 October 2002, to the intra-uterine device therapeutic subgroup, Contraceptive Devices therapeutic group as follows:

Formulation	Current Subsidy	Proposed Subsidy
Nova-T	\$39.50	\$28.00
Multiload Cu 375	\$39.50	\$28.00
Multiload Cu 375SL	\$39.50	\$28.00

Note: Subsidies are ex-manufacturer, exclusive of GST.

Prognova (oestradiol valerate)

1. PHARMAC proposes to amend, with effect from 1 October 2002, the terms of listing of Prognova (oestradiol valerate) 2mg tablet. The price and subsidy would be \$5.40 per 28 tablets (ex-manufacturer, exclusive of GST).
2. PHARMAC proposes to apply reference pricing with effect from 1 October 2002, to the Medium/High Dose therapeutic subgroup, Oestrogens therapeutic group as follows:

Formulation	Pack size	Brand	Current Subsidy	Proposed Subsidy
Oestradiol 2mg	28 tablets OP	Estrofem	\$7.00	\$5.40
Oestradiol valerate 2mg	28 tablets	Prognova	\$7.00	\$5.40

Note: Subsidies are ex-manufacturer, exclusive of GST.

Nuvelle (oestradiol with levonorgestrel)

1. PHARMAC proposes to amend, with effect from 1 October 2002, the terms of listing of Nuvelle tablets 2mg oestradiol with 75µg levonorgestrel (12 tablets) and 2mg oestradiol (16 tablets). The price and subsidy would be \$5.40 per 28 tablets (ex-manufacturer, exclusive of GST).
2. PHARMAC proposes to apply reference pricing with effect from 1 October 2002 to the Progestogen and oestrogen combined preparations therapeutic subgroups as follows:

Chemical	Formulation	Pack size	Brand	Current price	Current Subsidy	Proposed Subsidy
Oestradiol with levonorgestrel	Tab 2mg with 75µg levonorgestrel (12) and 2mg oestradiol tab (16)	28	Nuvelle	\$7.00	\$7.00	\$5.40
Oestradiol with norethisterone	Tab 1 mg with 0.5 mg norethisterone acetate	28 OP	Kliovance	\$11.45	\$7.00	\$5.40
Oestradiol with norethisterone	Tab 2 mg with 1 mg norethisterone acetate	28 OP	Cliane	\$11.45	\$7.00	\$5.40
Oestradiol with norethisterone	Tab 1 mg with 0.5 mg norethisterone acetate	28 OP	Kliogest	\$11.45	\$7.00	\$5.40
Oestradiol with norethisterone	Tab 2 mg with 1 mg norethisterone acetate	28 OP	Trisequens	\$10.00	\$7.00	\$5.40
Oestradiol with norethisterone	TDOS 50 µg (10) and 1 mg norethisterone tab (12)	1 OP	Estrapak	\$17.75	\$7.00	\$5.40
Oestrogen with medroxyprogesterone	Tab 625 µg conjugated equine with 2.5 mg medroxyprogesterone acetate tab (28)	28 OP	Premia 2.5 Continuous	\$11.45	\$7.00	\$5.40
Oestrogen with medroxyprogesterone	Tab 625 µg conjugated equine with 5 mg medroxyprogesterone acetate tab (28)	28 OP	Premia 5 Continuous	\$11.45	\$7.00	\$5.40
Oestrogen with medroxyprogesterone	Tab 625 µg conjugated equine (14), 625 µg conjugated equine 5 mg with medroxyprogesterone acetate tab (14)	28 OP	Premia 5	\$10.45	\$7.00	\$5.40
Oestrogen with medroxyprogesterone	Tab 625 µg conjugated equine (28) and 5 mg medroxyprogesterone acetate tab (28)	56 OP	Menoprem Continuous	\$11.00	\$7.00	\$5.40
Oestrogen with medroxyprogesterone	Tab 625 µg conjugated equine (28) and 10 mg medroxyprogesterone acetate tab (14)	42 OP	Menoprem	\$10.00	\$7.00	\$5.40
Oestrogen with norgestrel	Tab 625 µg conjugated equine (28) and 150 µg norgestrel tab (12)	40 OP	Prempak-C	\$7.75	\$7.00	\$5.40
Oestrogen with norgestrel	Tab 1.25 mg conjugated equine (28) and 150 µg norgestrel tab (12)	40 OP	Prempak-C	\$7.75	\$7.00	\$5.40

Note: Subsidies and prices are ex-manufacturer, exclusive of GST.

If you wish to make comments on this proposal, please forward them to PHARMAC by **5:00pm 14 August 2002**. A copy of this consultation letter will be available on PHARMAC's website www.pharmac.govt.nz until 14 August 2002. For queries, please contact David Goldsmith, Therapeutic Group Manager, in the first instance.

Yours sincerely

Wayne McNee
Chief Executive