Reproductive and Sexual Health Subcommittee of PTAC
Meeting held 28 July 2014

(minutes for web publishing)

Reproductive and Sexual Health Subcommittee minutes are published in accordance with the *Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and PTAC Subcommittees 2008*.

Note that this document is not necessarily a complete record of the Reproductive and Sexual Health Subcommittee meeting; only the relevant portions of the minutes relating to Reproductive and Sexual Health Subcommittee discussions about an Application or PHARMAC staff proposal that contain a recommendation are generally published.

The Reproductive and Sexual Health Subcommittee may:

(a) recommend that a pharmaceutical be listed by PHARMAC on the Pharmaceutical Schedule and the priority it gives to such a listing;

(b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or

(c) recommend that PHARMAC decline to list a pharmaceutical on the Pharmaceutical Schedule.

These Subcommittee minutes were reviewed by PTAC at its meeting on 6 & 7 November 2014.the record of which is now available on the PHARMAC website.

Record of the Reproductive and Sexual Health Subcommittee of PTAC meeting held at PHARMAC on 28 July 2014

1. Therapeutic Group Review

Contraceptives non Hormonal

1.1 The Subcommittee noted that there were no latex free condoms listed on the Schedule. The Subcommittee considered that it was not unusual for undiagnosed skin irritations to be diagnosed as latex allergies. The Subcommittee considered that the incidence of true latex allergy was <1%.

1.2 The Subcommittee considered that it remains important to have a latex free condom listed on the Pharmaceutical Schedule and access to these may be on a specialist documentation of a confirmed latex allergy. The Subcommittee noted that latex free condoms do not provide as effective STI prophylaxis as other condoms. The Subcommittee **recommended** that the opinion of the Dermatology Subcommittee be sought as to what formal documentation is required to confirm a latex allergy.

1.3 The Subcommittee **recommended with a high priority** that a male latex free condom should be listed on the Schedule in a range of available sizes.

1.4 The Subcommittee noted the wide range of condoms listed currently on the Pharmaceutical Schedule. The Subcommittee considered that sole supply of condoms per category (nominal width) was appropriate.

1.5 The Subcommittee considered 49, 56 and 60 mm nominal width latex condoms and flavoured condoms were the most pertinent sizes to list as sole supply.

1.6 The Subcommittee **recommended** that the New Zealand Aids Foundation be asked for their opinion about the clinical need for extra strength condoms to be listed.

1.7 The Subcommittee noted there was no lubricant listed on the Pharmaceutical Schedule. The Subcommittee considered that New Zealand MOH public health information recommends the use of suitable (not oil-based) lubricant, as male latex condoms are less likely to tear if water-based or silicone-based lubricants are used.

1.8 The Subcommittee considered that a non-irritant, water-based lubricant be considered on the Pharmaceutical Schedule as sole supply. The Subcommittee noted that a funding application would be required for the listing of a lubricant. The Subcommittee considered that the New Zealand Aids Foundation might be interested in submitting an application.

1.9 The Subcommittee **recommended** with a high priority that a non-irritant, water-based lubricant be listed on the Pharmaceutical Schedule

Hormonal Contraceptives

1.10 The Subcommittee noted that both the 20mcg and 30mcg ethinyloestradiol with 150mcg desogestrel strengths had been partially funded on the Pharmaceutical Schedule since 1995.

1.11 The Subcommittee noted that the European Medicines Agency report on OCs and VTE confirmed that there was a two-fold risk of Venous Thromboembolism (VTE) when taking COCs containing desogestrel compared with COCs containing levonorgestrel.. The Subcommittee considered that it was not appropriate that PHARMAC continue to fund this pharmaceutical.

1.12 The Subcommittee **recommended** with a low priority, based on clinical risk**,** the delisting of combined contraceptives containing desogestrel.

1.13 The Subcommittee noted that there was a 'new' 3 year LNG intra-uterine device that had been approved by Medsafe on 10 July 2014, called Jaydess®. Members noted that Jaydess was not registered for heavy menstrual bleeding. Members considered that a three year compared to a 5 year intra uterine system offered no advantage and noted the higher pregnancy rate reported with Jaydess. Members considered that there was no clinical advantage using this product in the treatment paradigm.

1.14 The Subcommittee considered that the number of patients that would switch to this treatment modality if it was fully funded would be small. Members considered that it would be difficult to state which product patients would switch from as this product did not provide significant advantages to patients over the currently funded comparable products. The Subcommittee **recommended** not listing Jaydess.

1.15 The Subcommittee noted the additional criteria that enable women to have the levonorgestrel intrauterine system (IUS) - Mirena funded for the indication of endometriosis does not enable the Mirena to be fitted at the time of laparoscopic diagnosis of endometriosis.

1.16 The Subcommittee **recommended** with a medium priority that PHARMAC determine a way for the Special Authority to enable the funded IUS to be inserted at the time of laparoscopy.

1.17 The Subcommittee noted that the Heavy Menstrual Bleeding (HMB) Guidelines don't exist anymore.

1.18 The Subcommittee **recommended** with a medium priority that the reference to the Heavy Menstrual Bleeding Guidelines is removed from the IUS criteria.

Imiquimod

1.19 The Subcommittee noted that PTAC, at its May 2014 meeting, recommended the removal of the Special Authority on imiquimod. The Subcommittee noted that there was a current consultation regarding the removal of the Special Authority for imiquimod.

1.20 The Subcommittee considered that most patients would respond to a one month treatment of imiquimod to treat external genital warts. One member noted that if patients did not respond to the one month of treatment, treatment modality and / or the diagnosis needed to be reviewed. The Subcommittee noted that the removal of the special authority would enable clinicians to prescribe up to 3 months of imiquimod without reviewing patient response to treatment.

1.21 The Subcommittee **recommended that the Special Authority for imiquimod be removed** with a medium priority. The Subcommittee considered they preferred a limit to patient treatment of one month at a time for genital warts.

Mefenamic acid

1.22 The Subcommittee noted that PHARMAC was investigating the possibility of fully funding mefanamic acid.

1.23 The Subcommittee considered that if it was fully funded, mefenamic acid would be used for primary dysmenorrhoea, dysfunctional uterine bleeding and pain or menorrhagia due to IUCDs. Members considered that the main use would be for primary dysmenorrhoea.

1.24 The Subcommittee considered that the main comparator treatments for primary dysmenorrhea would be other funded non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, diclofenac and naproxen.

1.25 The Subcommittee considered that there was very little evidence comparing mefenamic acid with other NSAIDs, noting a small trial showing no difference between ibuprofen and mefenamic acid in the treatment of dysmenorrhea (Roy S. Obstet Gynecol 1983;61:628-32), a systematic review which concluded that naproxen, ibuprofen, mefenamic acid and aspirin are all effective in primary dysmenorrhea with ibuprofen having the most favourable risk:benefit profile (Zhang and Li Wan Po. Br J Obstet Gynaecol 1998;105:780-9), and a Cochrane review of NSAIDs for heavy bleeding or pain associated with intrauterine-device use which noted that no important differences emerged in the one trial comparing the effect of different NSAIDs on bleeding (Grimes et al Cochrane Database Syst Rev. 2006 Oct 18;(4):CD006034).

1.26 The Subcommittee considered that oral contraceptives would be another alternative funded treatment option; however, members noted that this would not be appropriate or desirable in many cases.

1.27 The Subcommittee considered that mefenamic acid offered limited benefit over other funded NSAIDs in terms or efficacy or side effect profiles, but members agreed with the view of the Rheumatology Subcommittee that responses to NSAIDs are highly idiosyncratic so it is useful to have as many fully funded options as possible. The Subcommittee considered that approximately 20% of patients do not respond to ibuprofen in this setting.

1.28 The Subcommittee noted that successful treatment of primary dysmenorrhoea can be associated with a significant improvement in quality of life, and could also avoid or delay unnecessary laparoscopy.

1.29 The Subcommittee considered that there would be a significant financial risk associated with fully funding mefenamic acid at the current price without restrictions.

1.30 The Subcommittee considered that if mefenamic acid was more expensive than the alternative treatments it would be reasonable to restrict it to third-line treatment following a trial of two alternative treatments. Members considered that it would not be appropriate to require a trial of more than two prior treatments as this could lead to delays in assessment of patients with more serious problems while they cycle through multiple ineffective treatments.

1.31 The Subcommittee **recommended** that mefenamic acid be fully funded subject to Special Authority restrictions for patients with primary dysmenorrhoea, dysfunctional uterine bleeding and pain or menorrhagia due to IUCDs who have received insufficient clinical benefit from prior treatment with either two NSAIDs or one NSAID and an oral contraceptive. In the context of the endocrinology therapeutic area the Subcommittee considered this to be a low priority.

2 Female Condoms (FC2)

2.1 The Subcommittee considered an application from Glyde Healthcare Ltd for the listing of female condoms in Section B of the Pharmaceutical Schedule. The Subcommittee noted that the female condom FC2 was registered in New Zealand as a latex free non hormonal contraceptive The Subcommittee noted the indications for use on the application were as a contraceptive choice for women and for those individuals with latex intolerances and allergies.

2.2 The Subcommittee considered that the evidence provided in support of this application was of weak strength.

2.3 Members noted that while the application was for contraception, the main benefit of the female condom is the protection it provides for women from Sexually Transmitted Infections (STIs).

2.4 The Subcommittee noted (from sources outside the application), contraception data taken from tables in 'Contraception, your questions answered' (Guillebaud, J. 2013) and USA data from 'Contraception technology' (Hatcher et al, 2011) that the pregnancy rate with real life use of the female condom was 21% and 5 % with perfect use of the female condom. The Subcommittee considered that the female condom was not a highly effective contraceptive method but that its indication for use was to provide STI prophylaxis.

2.5 The Subcommittee considered that there was some unmet health need for those people with a latex allergy and for women seeking to protect themselves from STIs in situations where men will not use condoms. The Subcommittee noted that less than 1% of the population have a true latex allergy and therefore considered only small numbers of people would benefit from this feature of the female condom.

2.6 The Subcommittee **recommended** listing the female condom with a medium priority.

The decision criteria particularly relevant to this recommendation are:
(i) The health needs of all eligible people within New Zealand; (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (v) The cost – effectiveness of meting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services; (vii) The direct cost to health service users; (viii) The Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's funding agreement.