GREEN CROSS HEALTH

25 September 2015

Medicines Classification Committee Secretariat Medsafe
PO Box 5013
Wellington 6145

Dear Alyssa

Re: Objection to the 53rd meeting of the Medicines Classification Committee – supporting information

Both Green Cross Health and Natalie Gauld Ltd raised an objection to the rejection of reclassification of selected oral contraceptives at the 53rd meeting held on 5 May 2015. We believed a reconsideration of this reclassification is appropriate owing to a number of factors, and our objection was upheld as a result. This letter provides further supporting information.

Alternative option for consideration of supply of Oral Contraceptives by specifically trained pharmacists:

Firstly we would like to offer an alternative option if necessary for consideration by the committee, that supply is permitted by specially trained pharmacists only to women who have been **previously prescribed** oral contraceptives.

We continue to believe that initiation of oral contraception as well as supply to women who have had oral contraception previously is justified. The pilot studies in the UK[1] and US[2] showed that the model was safe and useful, and our proposed model outlined at the last MCC meeting is more restrictive than that legislated in the US states of California and Oregon allowing trained pharmacists to supply hormonal contraceptives including Depo-Provera for self-administration (see previous application for further information). We continue to have support from Associate Professor [redacted] and Associate Professor [redacted] the international expert on non-prescription contraception, for this position.

We also note that NZ pharmacists have taken their new services, including reclassifications, seriously, with evidence supporting this.[3-7] We provided evidence of delays in medical consultation being associated with unwanted pregnancies.[8] We proposed a collaborative approach with referrals to Family Planning and general practitioners for ongoing contraception discussions, sexually transmitted infection checks, and smear tests. However, after further consultation with the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) we suggest an alternative position, should the committee be willing to consider this, of pharmacists supplying only to women who have previously been prescribed an oral contraceptive. RANZCOG supports this model. RANZCOG is the major medical representative organisation that has specialist knowledge about contraception and pregnancy. Its members see unwanted pregnancies and conduct terminations that we wish to help avoid. We provided RANZCOG with seven scenarios:

1. NZ woman who has run out of her oral contraceptive
2. Woman visiting from overseas who has run out of her oral contraceptive
3. Woman receiving the emergency contraceptive pill who is a previous oral contraceptive user
4. Woman wanting to restart contraception who is a previous oral contraceptive user
5. Woman wanting post-partum contraception who is a previous oral contraceptive user
6. Woman receiving the emergency contraceptive pill who is oral contraceptive naïve
7. Woman who is oral contraceptive naïve who wants to start contraception

RANZCOG supported pharmacist-supply under all scenarios except the last two in which the woman has not had an oral contraceptive before. The possible wording for gazettal could rely on this as a requirement of the protocol for supply, in which case our suggested wording remains as below.

Ethinylestradiol	Restricted medicine when supplied at a strength of 35 µg or less in combination with levonorgestrel or norethisterone for the supply of oral contraception by a pharmacist who has successfully completed the training course for oral contraception, in accordance with the approved protocol for supply
Levonorgestrel	Restricted medicine when supplied for oral contraception by a pharmacist who has successfully completed the training course for the supply of oral contraception, in accordance with the approved protocol for supply, or in medicines for use as emergency post-coital contraception when in packs containing not more than 1.5 milligrams except when sold by nurses recognised by their professional body as having competency in the field of sexual and reproductive health
Norethisterone	Restricted medicine when supplied for oral contraception by a pharmacist who has successfully completed the training course for the supply of oral contraception, in accordance with the approved protocol for supply
Desogestrel	Restricted medicine when not in combination and when supplied for oral contraception by a pharmacist who has successfully completed the training course for the supply of oral contraception, in accordance with the approved protocol for supply

Alternatively all scenarios could add the words "to a woman who has previously been prescribed the oral contraceptive". We would expect the same training to occur and the screening tools would be adapted slightly to ensure women have been prescribed the oral contraceptive previously.

Chart 1 Categories of supply