29/2/2016

Medicines Classification Committee (MCC)

Medsafe

Ministry of Health

Wellington

CC: College of general Practitioners

**Re: The Reclassification of Selected Oral Contraceptives**

Women’s Health Action is a health promotion, information and consumer advisory service. We work with health professionals, policy makers and other not for profit organisations to influence and inform government policy and service delivery for women. We provide evidence-based analysis and advice to health providers, NGOs and DHBs, the Ministry of Health, and other public agencies on women’s health (including screening), public health, and gender and consumer issues with a focus on reducing inequalities.

We have made a previous submission on the proposal to Reclassify Oral Contraceptives (Application to Reclassify Oral Contraceptives, January 2015 by Green Cross Health and Pharma Projects Ltd).

We are extremely disappointed to hear that the MCC has received a further application for reclassification which was not made publically available without seeking additional comment from key stakeholders. We support the comments made by the Royal NZ College of General Practitioners in their letter of 9th February 2016. We believe MCC must undertake a full, transparent and robust consultation on this issue and are seriously concerned about the MCC’s processes so far.

**In regard to the proposal,** Women’s Health Action (WHA) agrees that access to affordable and available contraception needs to be improved, especially for certain groups such as young women and rural women. However it is essential that this is done safely and that patient rights to informed consent, privacy and equitable health care are protected. This includes the right to be seen by a properly trained health professional.

In 2014, Green Cross Health Ltd first applied to reclassify oral contraceptives. At this point questions were raised about integrated care, collaboration, pharmacist training, and pharmacist management of the patient. **We do not think the subsequent 2015 application has addressed all these issues in sufficient detail and believe the application should be refused at this time and other options to provide safe, affordable and accessible contraception to women and men be investigated.**

We are concerned about the following issues:

1. **The proposal will not improve access:**

We agree with NZ Family Planning (NZFP) that compared with pharmacists, Family Planning nurses are trained and well placed to prescribe contraceptive pills. A rapid way to improve access to contraception would be to allow more primary care nurses to prescribe contraception. Promoting this role for nurse practitioners in PHOs, particularly in areas without a Family Planning Clinic (FPC), or providing mobile family planning services in some areas, would provide more affordable access and may be less daunting than a doctor’s visit. There is also a need to provide culturally appropriate contraception and advice to some population groups.

1. **Addressing the cost of contraception**

The proposal does not indicate the costs that pharmacists would apply to this service and we believe the proposal contains no evidence that pharmacist supply will reduce costs for contraceptive users. Indeed it is probable the pharmacy fee plus the cost of the medication when not prescribed by a doctor will increase the cost above that currently charged by NZFP.

1. **Addressing health equity**

The proposal may improve access for women living in areas with limited access to GPs and Family Planning clinics and potentially, youth. However, disparities are not necessarily addressed if the services provided are not of the same standard as provided by a GP, primary care nurse or Family Planning clinic. There is no evidence that the priority groups for greater contraceptive access including young people, Māori and Pacific women and women with low incomes will necessarily benefit. More research and investigation is required in this area and in ascertaining the effects on health disparities.

1. **Ensuring professional behaviour**

There are no elements in this proposal that address the possibility of unprofessional behaviour by pharmacists in the context of them being alone in private rooms with female patients. There have been media reports and we have received several anecdotal reports of pharmacists taking a judgmental or inappropriate approach to providing emergency contraception, including asking intrusive questions about sexual behaviour. We are also concerned about the ability of some pharmacies to provide a private interview area. We are concerned there is no way of monitoring such incidents and none of the checks and balances in place for nurses and doctors are in place for pharmacists. We have some concerns that busy pharmacists may fail to find the time to undertake adequate assessment.

1. **Ensuring appropriate risk assessment**

As NZFP have noted, family violence screening is now routinely practiced in Family Planning and most primary health care practices in New Zealand. Women who see pharmacists will miss out on this screening and intervention. We also think a limitation of pharmacist-supply of oral contraceptives is the missed opportunity for opportunistic screening for a range of other health issues such as STIs, cervical smears, smoking cessation advice, alcohol advice, and discussion about general well-being and for ongoing monitoring of any side effects.

Similarly, we believe that it is common for patients and health professionals to find it difficult to assess certain risks, for example if a patient’s migraines are the type that contraindicate a combined oral contraceptive. We do not agree that women will necessarily recognise their contraindications or know the range of risk factors that should be assessed.

1. **Breastfeeding**

There is clear evidence that some forms of contraception should not be used while breastfeeding. We are concerned that a pharmacist may not be aware a woman is breastfeeding or may encourage stopping breastfeeding early to start on oral contraception. We are also concerned that pharmacists have an interest in promoting the use of infant formulas.

1. **Vested interests**

Pharmacists have a financial interest in selling these products and cannot be said to be immune to these and other commercial pressures.

**If the proposal should be accepted attention must be paid to the following issues:**

1. **Training programmes**

An approved, evaluated training programme followed by regular update sessions must be put in place. The programme must cover ethical issues, risk assessment and informed consent, assessment of high-risk women to ensure they do not receive oral contraception when they are at high risk of complications, teaching of pill-taking so that women use the packets correctly and know what to do if they forget pills, and information about STIs, use of condoms, cervical screening etc.

Pharmacists should be required to display evidence they have undertaken the programme.

1. **Age limit**

While we agree that young women have a right to contraception we believe this should be provided in the context of a full health assessment including monitoring of other issues such as family violence, coercion or STIs. Pharmacists should not be providing contraception to anyone under 16 or first time contraception to anyone under 18.

1. **Staged approach**

There should be a staged approach, which includes auditing by a doctor.

1. **COC and POPs**

Only the less risky POPs should be prescribed.

1. **Privacy**

Pharmacies must have a fit for purpose designated private room (i.e. not a store room or tea room), which is provided for interview for any form of contraception including emergency contraceptives.

1. **Informed consent**

The information materials we have reviewed are not entirely objective, are too long and set at a high literacy level. A robust information and informed consent process must be developed that is set at a lower literacy level, is accessible and clear. Information must also be provided verbally, in a language the patient can understand.

1. **Collaborative agreements**

We support the use of Collaborative Practice Agreements. The submission for the proposal mentions that many international pharmacist-supply programmes for oral contraception involve collaborative practice agreements where the pharmacist works with a doctor. We also agree initial audit by a doctor, should be an essential part of any training programme.

In conclusion, Women’s Health Action agrees that access to contraception must be improved, especially for certain groups such as young women. However, we do not think that this proposal is a safe or effective way of doing so.

We believe that contraception should be provided in the context of overall health care, assessment of risk factors and ongoing monitoring. While seeming to offer an advance in healthcare for women, this proposal in fact is likely to result in more costly and less effective health care and to increase risk. As such we share the RNZCGP’s concerns.

While it is not in the domain of the MCC to make such decisions, we would prefer to see increased family planning and PHO resources put in place and that contraception be provided free of charge to New Zealand women.