Submission for Reclassification of Selected Oral Contraceptives

Executive Summary

Oral contraceptives are one of the most used, most studied, and most effective medicines in use today. Oral contraceptives provide protection against unintended pregnancy, with a side effect profile that is consistent with non-prescription availability.[1] They also meet other criteria for non-prescription availability, such as low risk in overdose and low potential for misuse and abuse, a woman can determine whether she needs contraception or not, and dosage is straight-forward.[2] Furthermore, pharmacy studies in the UK[3] and the US[4] have shown that women can receive safe supply through specially trained pharmacists.

The American College of Obstetricians and Gynecologists Committee on Gynecologic Practice publicly supported non-prescription supply for oral contraceptives in 2012 with a public paper.[5] The American Academy of Family Physicians followed with their support in 2014.[6] Californian legislators agreed and hormonal contraception will shortly be available without a prescription through pharmacists there.

Already some pharmacist-supplies occur without a doctor's prescription in the United States (US), United Kingdom (UK), and Australia. In some US states, community pharmacists supply oral contraceptives directly to women without a doctor's prescription, either continuing the woman's current therapy or initiating therapy under collaborative practice agreements.[7] In the UK, patient group directions (PGD) are available for community pharmacists to provide oral contraceptives without a doctor's prescription.[8] Australia has a continuation supply provision.[9]

Consumer research shows women in the US,[10-12] Australia,[13] and NZ[14] want non-prescription access to oral contraceptives.

Many women will appreciate the greater accessibility and convenience from pharmacist-supply of oral contraceptives. Pharmacies typically have longer opening hours than GPs, convenient locations and provide a walk-in service without appointment. Reclassification means that when a woman runs out of her tablets she can access more without a prescription and does not risk missing tablets. Reclassification may reduce the barriers to starting contraception. Therefore, reclassification has the potential to reduce unintended pregnancies, providing a significant public health benefit. Women obtaining the Emergency Contraceptive Pill (ECP) from pharmacy would benefit from immediate access to effective ongoing contraception.

Women can already access the emergency contraceptive pill from pharmacists in New Zealand, providing a model of care for this proposal. Pharmacists must undergo specific training to supply the medicine, and typically use a checklist for supply.

In 2014, Green Cross Health Ltd and Pharma Projects (now Natalie Gauld Ltd) applied to reclassify oral contraceptives. We proposed a very strict and careful model that requires additional pharmacist training, use of a special screening tool, written and verbal information

to be given to the woman, and informing the woman's general practitioner (GP) with patient consent. The Medicines Classification Committee in 2014 agreed that *"the risk:benefit profile of oral contraceptives was similar to other restricted medicines."*[15] However, the committee wanted to see more medical input into the reclassification. This input occurred, but the committee rejected the application in April 2015. After an objection, the reclassification was reconsidered at the November 2015 meeting with alternate proposals suggested, resulting in a positive decision. An ensuing objection in early 2016 saw a reconsideration in May 2016, resulting in a call for a further application, consultation and a proposal for the November 2016 MCC meeting. We have undertaken further consultation, and have a new proposed classification. We note that the MCC is able to make changes to the classification statement without further consultation.

The MCC in November 2015 made the following recommendation:

> *That the selected oral contraceptives (desogestrel, ethinylestradiol, norethisterone and levonorgestrel) should be reclassified as restricted medicines, when sold in the manufacturer's original pack containing not more than six months' supply by a registered pharmacist who has successfully completed a training programme (endorsed or accredited by an organisation that is to be confirmed as stated in the following recommendation), when indicated for oral contraception in women who have previously been prescribed an oral contraceptive within the last 3 years from the date of an original medical practitioner's prescription.*
>
> *That Green Cross Healthcare Limited should provide Medsafe with details of who will be responsible for accrediting the training programme and maintaining and enforcing the provisions under which a pharmacist with additional competencies could prescribe selected oral contraceptives.*
>
> *That Green Cross Healthcare Limited should update Medsafe of the changes required to the training and monitoring procedures to reflect the Committee's recommendations.*
>
> *That market sales should be collected and analysed to monitor the success of the scheme in improving access to oral contraceptive pills. The Committee is interested in being updated on the outcomes of this recommendation.*

This application requests a reclassification of selected oral contraceptives to allow supply without prescription by pharmacists who have successfully completed an approved training course, and are complying with approved guidelines.

Introduction

This application for reclassification follows a series of considerations at the Medicines Classification Committee. An initial application was made in 2014, and was rejected. A second application was made in 2015 and rejected by the committee. An objection was lodged and upheld, and an alternate proposal was suggested by the objectors. The following consideration resulted in a recommendation for reclassification by the committee, where women had been prescribed an oral contraceptive by a doctor in the last three years. A further objection followed, on the basis of process, and another consideration occurred. The committee noted confusion and requested a new application be submitted so that it is clear that consultation can occur around what is proposed. However, we note that the committee has the prerogative to recommend something different to what is proposed without undertaking further consultation.

This application takes on board the comments from the Medicines Classification Committee, and the Royal Australia and New Zealand College of Obstetricians and Gynaecologists which recommended supply by pharmacists where the woman had had oral contraceptives prescribed previously. We have consulted or attempted to consult with various organisations in this application (as per a confidential appendix), and/or considered the comments of all submissions to the Medicines Classification Committee except those for the first consideration which are not published.

The proposal therefore is for supply to women who have been prescribed an oral contraceptive in the past three years by a doctor. The full screening, in accordance with World Health Organisation Medical Eligibility Criteria for contraceptives, will take place through a pharmacist who has been specially trained, before any non-prescription supply in any pharmacy. The full screening will be repeated annually. In line with the previous MCC recommendation (November 2015 meeting), we suggest a six-month period of supply be allowed. Further details are within this application. Women who have been prescribed any oral contraceptive in the last three years could be continued on the same oral contraceptive (providing it was one mentioned in this application). Alternatively, where a break in treatment had occurred, or the woman had last been prescribed it overseas, could change to another oral contraceptive if more suitable (e.g. post-partum and breast-feeding). Pharmacists would inform the GP of supply with the patient permission, or refer to the GP or Family Planning if supply was not suitable, or for other contraceptive options.

The screening tools and information sheets used have been developed according to WHO MEC criteria, and in consultation with specialists in the area as well as general practitioners (GPs) and pharmacists. These include checks for contraindications, precautions, adverse reactions, compliance, and prompts for verbal advice on the oral contraceptive and sexual health. The training would be provided by the Pharmaceutical Society of New Zealand, who are well respected for their training provision for pharmacists, using experts in the field.

Pharmacists are trained health professionals. To become a pharmacist, a person must successfully complete a four-year Pharmacy degree at university then an internship, typically in community pharmacy or hospital pharmacy. They have further learning during their internship and must successfully pass the requirements of their internship to then become

registered as a pharmacist. Pharmacists are registered health professionals with a Code of Ethics and a registering body (the Pharmacy Council), they have to work within NZ legislation such as the Medicines Act and Regulations, and the Code of Health and Disability Services Consumers' Rights and there are additional protocols they need to work within specific to pharmacy. They are required to complete continuing professional development and ensure they have competency for the services they provide. They take responsibility for the services they provide.

Pharmacists have taken their work with reclassified medicines seriously and welcomed the ability to better serve their communities with the reclassifications of the emergency contraceptive pill, trimethoprim and vaccinations, and provision of INR testing for warfarin, for example.

Part A

Note: Throughout this application the terms OC refers to oral contraceptives, POP refers to progestogen-only contraceptives, and COC to combined oral contraceptives (i.e. containing an oestrogen and a progestogen).

1. **International Non-proprietary Name (or British Approved Name or US Adopted Name) of the medicine**

Combined oral contraceptives (COC)

Ethinylestradiol with norethisterone

Ethinylestradiol with levonorgestrel

Progestogen only pills (POP)

Norethisterone

Levonorgestrel

Desogestrel

2. **Proprietary name(s)**

	Funded	**Unfunded but have datasheets on Medsafe website**
Combined oral contraceptive		
Ethinylestradiol 35 µg with norethisterone 500 µg	Brevinor, Norimin	
Ethinylestradiol 35 µg with norethisterone 1 mg	Brevinor 1	
Ethinylestradiol 30 µg with levonorgestrel 150 µg	Ava 30	Levlen, Microgynon 30, Monofeme*, Roxanne 30/150*, Nordette*
Ethinylestradiol 20 µg with levonorgestrel 100 µg	Ava 20	Microgynon 20, Roxanne 20/100*, Loette*
Progestogen only pill		
Norethisterone 350 µg	Noriday	
Levonorgestrel 30 µg		Microlut
Desogestrel 75 µg		Cerazette

*Not stocked with ProPharma, probably discontinued or never marketed

We have taken expert advice in choosing these oral contraceptives from the full range to minimise risk to users. Further information on risk is provided in our initial application, but has not been repeated as experts have advised this is appropriate.

3. Name of company/organisation/individual requesting reclassification

Green Cross Health Ltd and Natalie Gauld Ltd. Green Cross Health is the parent company for over 300 Life and Unichem Pharmacies in New Zealand. These pharmacies are located throughout New Zealand in malls, in and adjacent to medical centres and in suburban shopping strips both rurally and in central cities. In line with other reclassifications, this reclassification will allow pharmacists in New Zealand who meet the criteria to supply oral contraception in any New Zealand pharmacy.

4. Dose form(s) and strength(s) for which a change is sought

Dose form: Tablets.

The strength would only be specified for ethinylestradiol as ≤35 µg because higher doses are available for contraception that we consider should only be prescribed by an authorised prescriber.

5. Pack size and other qualifications

Oral contraceptives typically come in three month packs. There would be no pack size qualifications. The guidelines would limit pharmacist-supply to no more than six months' supply at one consultation.

There are no other qualifications other than what is stated below: the need for the pharmacist to successfully complete training and assessment; the need for use in contraception only; and the need to supply only in accordance with the approved protocol for supply.

6. Indications for which change is sought

Oral contraception. Note, this excludes supplies in which the primary reason for supply is for non-contraceptive reasons.

7. Present classification of medicine

Levonorgestrel has the following classification:

Prescription: except when specified elsewhere in this schedule; except in medicines for use as emergency post-coital contraception when sold by nurses recognised by their professional body as having competency in the field of sexual and reproductive health

Restricted: 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

The other ingredients listed above are prescription medicines

8. Classification sought

Ethinylestradiol	Prescription medicine except when supplied at a strength of 35 μg or less in combination with levonorgestrel or norethisterone when supplied in the manufacturer's original pack for the supply of oral contraception by a pharmacist who has successfully completed a training programme endorsed by the Pharmaceutical Society of New Zealand for this purpose.
Levonorgestrel	Prescription medicine except when supplied in the manufacturer's original pack for oral contraception by a pharmacist who has successfully completed a training programme endorsed by the Pharmaceutical Society of New Zealand for this purpose. Restricted medicine 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	Prescription medicine except when supplied in the manufacturer's original pack for oral contraception by a pharmacist who has successfully completed a training programme endorsed by the Pharmaceutical Society of New Zealand for this purpose
Desogestrel	Prescription medicine except when not in combination and when supplied in the manufacturer's original pack for oral contraception by a pharmacist who has successfully completed a training programme endorsed by the Pharmaceutical Society of New Zealand for this purpose

A prescription except when category has been chosen to ensure continuation of the brand the woman is used to wherever possible and to minimise the difficulties for manufacturers who have to manage stock for the small New Zealand market which often requires international packs and supplies of many months in stock which would require over-labelling. The prescription packs contain a pack insert (current consumer medicines information) and the pharmacist would provide an additional information sheet specific to non-prescription supply.

Other requirements around the supply are as follows:

1. That where there has been no break in therapy, the same formulation is continued, unless that formulation is not available in NZ
2. If there has been a gap in therapy or the formulation is not available in NZ, the therapy may change, e.g. where a woman stopped treatment, had a baby and now is post-partum and breast-feeding

3. That supply can only occur if the woman is eligible for supply in accordance with the screening tool consistent with World Health Organisation's Medical Eligibility Criteria for contraceptives, and approved by the MCC (or Pharmaceutical Society of New Zealand, as the MCC sees fit)
4. Doctor referral occurs where the woman is ineligible according to the screening tool
5. A full rescreening is undertaken at first visit to a pharmacy, and annually if required
6. A maximum of 6 months' supply can be provided
7. The woman needs to have been prescribed an oral contraceptive in the past three years by a doctor (based on prescription or first dispensing date)
8. The woman's GP is informed of the supply unless the woman opts out of this process
9. Verbal and/or written information is supplied on the need for smear tests, sexually transmitted infection checks (if necessary), contraceptive options including long-acting reversible contraception, compliance, adverse effects, and what to do if a tablet is missed or diarrhoea or vomiting occur.

The Pharmacy Council Protocol for the Sale and Supply of Pharmacist Only Medicines for Chronic conditions would also apply to the pharmacist supply of oral contraceptives. See http://www.pharmacycouncil.org.nz/cms_show_download.php?id=212 This protocol includes:

- Face-to-face consultations when possible unless due to disability or geographical isolation within New Zealand this is impractical
- No pharmacist-supply to patients who reside outside of New Zealand unless a face-to-face consultation occurs
- A requirement to exercise professional judgement to prevent the supply of medicines that are unnecessary or in excess to the patient's needs
- Electronic record-keeping of the supply of the medicine and records of the consultation
- Follow-up information is collected and added to the patient's record
- Other health practitioners caring for the patient are referred to or consulted with if necessary and with the patient's permission
- Privacy requirements
- The need to determine the appropriateness of the medicine
- Advising the patient using verbal and appropriate written information

9. Classification status in other countries (especially Australia, UK, USA, Canada)

The oral contraceptive is a prescription medicine in Australia, the UK, and the USA. However, pharmacist-supply of oral contraceptives occurs in all three countries.

In California, new legislation has allowed pharmacist supply of oral contraceptives without a doctor's prescription or collaborative agreement. This legislation removes the need for a collaborative agreement with a prescriber. Other US states have followed suit.

In Australia, since 1 September 2013, a Continued Dispensing initiative allows pharmacists to supply oral hormonal contraceptives.

In the Netherlands, after a single prescription for an oral contraceptive, the same oral contraceptive can be supplied indefinitely by the pharmacist.

Countries in which oral contraceptives are legally available without prescription with screening required include South Africa, Vietnam, Malaysia and Jamaica.[16] Countries in which oral contraceptives are legally available without prescription and with no screening required include Greece, Kuwait, South Korea, Thailand, Egypt, Bosnia and Herzegovina, and Hong Kong. Dr Dan Grossman from Ibis Reproductive Health provided useful insights into this area at the previous MCC meeting and shared the model of care currently used for Oral Contraceptives within some states of the US.

10. Extent of usage in New Zealand and elsewhere (e.g. sales volumes) and dates of original consent to distribute

See Appendix 1 for usage.

Brevinor – ethinylestradiol with norethisterone was consented in 1976

Microgynon – ethinylestradiol with levonorgestrel was consented in 1974, with the low dose version in 1999

Noriday – norethisterone was consented in 1972

Microlut – levonorgestrel was consented in 1973

Cerazette – desogestrel was consented in 1999

11. Labelling or draft labelling for the proposed new presentation(s)

Labelling would not change for the proposed reclassification. The pharmacist would supply in current packaging with an additional information sheet.

12. Proposed warning statements if applicable

Current packaging would remain. Patient information sheets have been developed for each of combined oral contraceptives and the progestogen-only pill.

13. Other products containing the same active ingredient(s) and which would be affected by the proposed change.

No other products are affected.

Part B

Support for reclassification of the oral contraceptive has occurred since the 1970s. This call has been strengthening in recent years, including through collection of evidence to help open access further. Quotes of these were provided in the previous application (p9), and include papers in the Lancet[17,18] and a medical organisation from the US (as below).

In 2012, the American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice stated:[5]

> ***"Weighing the risks versus the benefits based on currently available data, OCs should be available over-the-counter."***

Since our application, more support for non-prescription oral contraceptives has been seen in the US, and some support has emerged in NZ, although other medical organisations in NZ have been opposed to the idea.

In 2014, The American Academy of Family Physicians put out a public statement in support of non-prescription access:[6]

> ***"The AAFP supports over-the-counter access to oral contraception without a prescription."***

For the last meeting, a submission from the Royal Australian and New Zealand College of Obstetrics and Gynaecology supported pharmacist-supply as follows:[19]

> ***"We believe that it would be effective to allow appropriately trained and accredited pharmacists working in suitable premises (ie with an appropriate, private space available for discussion and clinical checks) to write repeat prescriptions for the oral contraceptives listed at item 6.1 on your agenda.***
>
> ***We support the proposed reclassification of those four medicines from prescription to restricted."***

1. A statement of the benefits to both the consumer and to the public expected from the proposed change

The primary aim of reclassification is to improve women's access to effective contraception, and to provide access consistent with the safety and efficacy of this medicine. Availability through specifically trained pharmacists under strict criteria reduces barriers to access for women whilst maximising safety, and has the potential to reduce the risk of unwanted pregnancy. Secondary benefits are likely.

The COC and POP are effective in preventing pregnancy. The COC and POP have a failure rate of 0.3% in the first year of use with perfect use.[20] With typical use this rate rises to 8%. These rates compare very favourably to 85% pregnancy in sexually active women with no

contraceptive method. The condom has a 2% (perfect use) and 15% (typical use) failure rate. The long-acting depot medroxyprogesterone injection has a 0.3% (perfect use) and 3% (typical use) failure rate. Some other LARCs have lower rates of pregnancy. Intra-uterine devises have 0.2-0.8% failure rates. Fertility awareness-based methods have a 25% typical use failure rate, and withdrawal is slightly higher at 27%.

Allowing supply through specifically trained pharmacists will encourage women to access this medicine more easily, particularly following ECP use, while retaining safety in usage.

Increased access should help:

- women who have run out of tablets (a proven reason for discontinuation of this medication)[13]
- women who cannot easily get to their doctor before their resupply is due (eg women who cannot at this time take a half day off to see their doctor)
- visitors to NZ who need a resupply
- women who are away from home and forgot to take their tablets
- women who have barriers to doctor or family planning access for contraception (e.g. teenagers, see below) providing they have been prescribed it in the past three years
- women presenting for the emergency contraceptive pill, who can be offered oral contraception to start immediately (if they have been prescribed it in the past three years)
- women who are not using effective contraception currently (if they have been prescribed it in the past three years)
- women who have a new partner and have become sexually active again (if they have been prescribed it in the past three years)
- reassure women of the safety and benefits of these medicines
- reduce unintended pregnancies and termination of pregnancy

While publicly available figures are not readily available for ECP use in NZ, the Medicines Classification Committee at the last meeting was reportedly provided with information that showed an increase in ECP use through the pharmacist while GP or family planning supply had remained stable, indicating that reclassification was satisfying an unmet need. The minutes reported that "the committee noted that this could potentially equate to an unmet need for the supply of oral contraceptives without a prescription." [15]

It may increase realisation of other benefits of the oral contraceptive, such as reduced incidence of ovarian cancer.[17]

Reduced risk of unprotected intercourse

This was covered in our previous application (p12). In brief, women seeking termination of pregnancy often cite difficulty of procuring contraception.[21] Furthermore, women run out of contraceptive tablets which causes some to temporarily discontinue taking them.[13] Landau and colleagues in the US estimated that half a million fewer unintended pregnancies would occur each year if contraceptive pills, patch and ring were available through pharmacies.[22]

Non-contraceptive benefits of oral contraceptive

While reclassification would only be for contraceptive purposes, the combined oral contraceptive has other benefits, such as reduced risk of ovarian cancer, and endometrial cancer. A UK observational study found that women who took oral contraceptives lived longer than women who did not.[23] Further secondary benefits were provided in the initial application (p13).

Acceptability of non-prescription availability

International[12,13] and New Zealand evidence[14] shows that oral contraception through the pharmacy is wanted by many women. Furthermore, evidence suggests that pharmacy availability would help address a current gap in contraception access.

In a survey of women supplied oral contraceptives in London through pharmacist-supply, 11% stated they would not have accessed contraception elsewhere.[3]

In the US, surveyed women aged 18-44 years were very supportive of pharmacy availability of oral contraception, the contraceptive ring or the contraceptive patch, citing convenient hours (85%), convenient locations (84%) and time (82%) and cost savings (76%).[22] Forty-one per cent of women who were not using any contraception said they would begin using a hormonal contraceptive if accessible from the pharmacy. Three-quarters of the women said pharmacists should provide advice on these medicines, and many considered pharmacist screening should occur.

Many women in El Paso, a Texan city near the Mexican border, obtain their oral contraceptives from Mexico without a prescription – largely for reasons of convenience and cost.[24]

A survey undertaken with 1567 female consumers in December 2012 on the NZ Girl site, asked if they wanted more health services through their pharmacist.[14] Nine per cent volunteered, unprompted, that they wanted the oral contraceptive available in that way.

US health professional organisations have added public support to non-prescription availability of oral contraceptives. In 2011, the Women's Health Practice and Research Network of the American College of Clinical Pharmacy supported reclassifying the oral contraceptive.[25] This group noted that the oral contraceptives meet safety criteria for OTC products, literature demonstrates women can self-screen for contraindications, and experience with OTC emergency contraception suggests that OTC oral contraceptives would not increase sexual risk-taking behaviour. In December 2012, the American College of Obstetrics and Gynecology released a Committee opinion supporting this (see below for further details).[5]

The American Academy of Family Physicians also put out a statement in support of non-prescription access to oral contraception.[6]

Increased options for women of different ethnicities

In New Zealand, Asian women are less likely to consult the doctor for contraception than other ethnicities are. One 2002 study found 80% of Asian women presenting to an Auckland clinic for abortion had not used any contraception pre-conception.[26] The Asian women were commonly non-residents (e.g. students) or had recently immigrated to New Zealand, and the authors noted the need for sexual health education in these groups. Women in China and Hong Kong can access the oral contraceptive without prescription, and so absence of such availability in New Zealand may affect continuing usage. A later New Zealand study found that fewer Asian women used the oral contraceptive before having an abortion than other ethnicities, but following the abortion, oral contraceptive use increases to a similar rate to other ethnicities,[27] perhaps suggesting a role of education and access for this population.

New Zealand government strategy

Non-prescription supply of the COC and POP by approved pharmacists is clearly in line with the government strategy of "Better, Sooner, More Convenient healthcare", providing a more accessible option.

Population growth, an ageing population and developments in health are increasing demand for health services in a constrained fiscal environment. These require better use of the existing health workforce, including extending existing roles.[28] Having oral contraceptives available through specifically trained pharmacists without a prescription will help meet this need. Furthermore, increasing knowledge amongst pharmacists about oral contraceptives aids their role with the prescription supply of these medicines. Changes in Government policy such as the availability of free access to under 13's as of July 2015 will place further stress on primary care. There is a definite need to continue to drive those professions such as pharmacists to be able to operate at the top of their scope of practice to cope with additional demands on other sectors. As Dr Bev O'Keefe said in 2012 when Chair of General Practice New Zealand, there are opportunities for general practice to "adopt a proactive mantle akin to that of community pharmacy" to have GPs working at the top of their scopes of practice and relieve some of the burden from above.[29]

Internet access

Oral contraceptives, Intra Uterine Devices (IUDs) and contraceptive implants have been found available online, with IUDs having "how to" videos on You tube to aid insertion,[30] and with supply of oral contraceptives to women stating serious risk factors in the on-line screening.[31] While we do not know how many women from New Zealand are accessing such medicines, it is likely that some will be accessing oral contraceptives, which may be counterfeit and would be unlikely to have appropriate screening. Non-prescription supply is convenient and immediate, so may reduce interest in on-line procurement.

Pharmacy availability

Access to the COC and POP would improve because pharmacies are convenient and accessible, with no appointment usually necessary, extended hours, and over 950 pharmacies

throughout New Zealand. Women would have easy access to the pharmacist by telephone or visit after initial supply, without the need for an appointment, and often seven days a week. If more women had easy access to health providers who had up-to-date knowledge on managing common concerns in New Zealand women about contraception, it is possible that this could help continuation of therapy.

Improving contraception among emergency contraceptive pill users

Currently women receiving the ECP in pharmacy cannot be offered contraception on the spot apart from condoms, which do not suit everybody, have a higher pregnancy rate than oral contraceptives,[20] and may be the reason for the presentation (condom failure). Advice to see a doctor for other contraception may take time to action, potentially delaying start on effective contraception and allowing for the risk of an unplanned pregnancy.

Women will benefit from having an informed discussion about ongoing contraception with the pharmacist on receiving the ECP. Women will also receive written information – one information sheet about different types of contraception and general important information (including regular doctor visits), and information specific to the contraception provided (if any is provided).

Women can easily access community pharmacies and most use pharmacies already for other services. Suitable women will have greater access to oral contraceptives through trained pharmacists. This reclassification initiative fits well with both sexual and urinary health medicines that are already available through pharmacists. Patients are triaged every day to general practice and family planning for a variety of reasons that include STI checks and the need for further medical advice.

2. Ease of self-diagnosis or diagnosis by a pharmacist for the condition indicated

A diagnosis is not required to decide if contraception is needed. Women will be best-placed to know whether or not they are having sexual intercourse. Pharmacists will be able to provide guidance in the discussion as well as written information.

3. Relevant comparative data for like compounds

The emergency contraceptive pill or ECP, containing levonorgestrel, has been available in New Zealand since the early 2000s. Unlike most other countries, the patient's care is maximised in New Zealand through mandatory training for pharmacists who become accredited to supply the ECP. Women can access the ECP from most New Zealand community pharmacists who have become accredited to supply the ECP. There is no mandate for updates at certain intervals with the ECP, although the New Zealand College of Pharmacists has offered an update. Further patient protection and encouragement of best practice is assured by consultation forms which have been available since the reclassification, and are often used as an aide memoire as well as a record of the consultation. There is no requirement to advise the woman's doctor of the supply.

Some other contraceptive measures do not require a prescription. Women and men can access condoms and are available with no health professional involvement and no screening.

Condoms have a higher failure rate than the oral contraceptive – 2% in the first year with perfect use, and 15% in the first year with typical use.[20] The failure rate is highest with persons under 25 years. Diaphragms and spermicides do not require a prescription. Other means have been used to prevent pregnancy, such as withdrawal, and the rhythm method (or natural family planning). These both have higher risk of pregnancy than oral contraceptives, and provide no protection against STIs.

4. Local data or special considerations relating to New Zealand

New Zealand has an ageing population and increasing pressure on health resources.[32] A workforce survey shows that the general practitioner workforce is aging and the number of full-time GPs per head of population in NZ is declining.[33]

Workforce New Zealand has suggested the health workforce needs to work at the top of their scopes of practice,[28] and supply of oral contraception by pharmacists who have undergone additional training fits this desire.

Recent NZ data[34] confirms studies from elsewhere, that unplanned pregnancy is related to increased levels of adverse family socioeconomic circumstances, increased levels of family dysfunction, and poorer parent–child relationships.

We addressed barriers to access in our initial submission. Additionally, RANZCOG, Dame Margaret Sparrow, and ALRANZ have all highlighted barriers to access of contraception in NZ in their earlier submissions. In New Zealand, Asian women are less likely to consult the doctor for contraception than other ethnicities are. One 2002 study found 80% of Asian women presenting to an Auckland clinic for abortion had not used any contraception pre-conception.[26] The Asian women were commonly non-residents (e.g. students) or had recently immigrated to New Zealand, and the authors noted the need for sexual health education in these groups. Women in China and Hong Kong can access the oral contraceptive without prescription, and so absence of such availability in New Zealand may affect continuing usage. Other studies support barriers to access of healthcare for recent migrants and the lower likelihood of Asian women seeing the doctor about contraception. Many pharmacies in NZ have pharmacists or other staff able to speak multiple languages and overcome the language barrier for these women, and there is an opportunity to provide an oral contraceptive and then help them find a local general practitioner or Family Planning Association clinic for their on-going needs.

Women (n=22) attending Waikato Hospital for a termination of pregnancy in 2009 six months or less after a live birth provided insight into contraceptive access.[35] Barriers to accessing contraception included: transport, shame/embarrassment (whakamaa), living in a rural area, side effects, “forgot”, being “too busy”, time-poor or with child-care issues, on waiting lists for IUD or sterilization, and that the midwife did not offer contraception. Most of these can be helped by supply from a community pharmacist.

Records for women having a termination of pregnancy in Wellington from 2006-2010 were analysed with a particular focus on 305 Chinese women.[27] Many (41%) had had a termination of pregnancy before, and 93% were overseas-born (versus 78% of the Chinese population in NZ). Chinese women who had been in New Zealand for less than two years had the highest non-use of contraception pre-termination (73%). Counselling increased the use in Chinese women of the oral contraceptive (47%) and IUD (29%) after the termination. The authors noted that, given other research that showed barriers to access of healthcare for recent migrants and the lower likelihood of Asian women seeing the doctor about contraception, "it is perhaps not surprising that Chinese migrants in New Zealand have a lower use of contraceptive methods requiring a GP visit and prescription, so rely on condoms and behavioral methods of contraception." Furthermore, they concluded: "We suggest there is an unmet need for provision of contraceptive information to migrant Chinese women in New Zealand. With increasing numbers of reproductive aged Chinese migrants expected in New Zealand over the next ten to fifteen years, it is important that strategies are implemented to ensure women are educated about, and aware of contraceptive options before they face an unwanted pregnancy." In many of the countries these women came from, oral contraceptives are available without a prescription, so reclassifications may particularly increase uptake for this group.

While the termination of pregnancy rate for New Zealand has been declining since about 2003, particularly in women 15-24 years of age, 13,137 were still performed in 2014.[36] A comparison from 2013 found the NZ rate of 15.6 abortions per 1000 women aged 15-44 years was higher than the Netherlands (8.5), Finland (10.4), Scotland (11.2), Denmark (14.3), and Norway (14.7). Notably, 55% of women getting a termination in NZ reported no use of contraception, 25% reported condoms, and 14% reported combined oral contraceptive or progestogen only pills. A small but important 1.5% reported using the emergency contraceptive pill. Pharmacists are already helping to address the termination rate with funded emergency contraceptives to young women in some regions of the country. Pharmacists want to help reduce terminations (and unplanned continued pregnancies) further with a reclassification of the oral contraceptive to improve access for women.

A TV3 news poll in 2015 found 81% of respondents wanted oral contraceptives from the pharmacist.

Youth health

New Zealand has a very high rate of teenage pregnancies particularly in Māori (70/1000) and Pacific women (44/1000) contributing further to health disparities. As Statistics NZ notes: Teenage childbearing is generally considered a poor life choice. It is widely acknowledged that the responsibilities of early parenthood have long-lasting effects on the socio-economic wellbeing of the women and children involved. This results in part from interrupted education; failure to attain educational potential; reduced earning potential; reduced career

prospects; and, more generally, simply being emotionally and socially unprepared for childrearing.

A study of secondary school students in 2012[37] found that 19% of students had been unable to access healthcare when they needed to sometime in the last 12 months, particularly for high deprivation neighbourhoods. For 28% this was because of a lack of transport, and 46% did not want to make a fuss. Of students who accessed healthcare in the last 12 months (including 74% who saw a family doctor), only 37% had a chance to talk to the doctor or other health professional in private. Any pharmacy can be visited without their parent, and youth are not restricted to the one they are enrolled in but can visit the pharmacy nearest them when it suits them. Of those students who were currently sexually active, only 58% used contraception all of the time. Schools vary considerably in what sexual health services they offer, with fewer than half of schools with a health professional or health team on site offering oral or injectable contraceptives and many schools having only visiting health professionals, or first aid only with no health professional available. Even where schools have an on-site health professional, holidays are not covered.

The New Zealand population is becoming increasingly diverse in ethnicities and languages. Pharmacies often have staff who speak languages that are common in their community, such as Vietnamese, Cantonese, Samoan and Gujarati. Pharmacists are expected to be culturally aware and courses are offered on this.

5. Interactions with other medicines

Women who may have a drug interaction with another medicine will be identified as these are included in the screening tool, and in training.

Important interactions include CYP3A4 enzyme inducers, such as certain anticonvulsants and rifampicin, and will be screened for, with referral for contraceptive advice. When considering other medication, they will also be thinking about implications other than interactions, e.g. antihypertensives signal a contraindication, hypoglycaemics signal diabetes and therefore a doctor referral, and HIV medication signals issues around potentially transmitting the virus (as well as interactions). This is common sense to pharmacists who use this in other non-prescription supplies. However, it will be covered in training.

Antibacterials that are not enzyme-inducing are now considered not to interact with oral contraceptives unless they cause vomiting and/or diarrhoea which may reduce the absorption of oral contraceptives.

Stockley's Drug Interactions reports the following medicines interact with the COC:

- Rifampicin
- Rifabutin
- Phenytoin
- Oxcarbazepine
- Carbamazepine
- Phenobarbital and primidone

- Rufinamide
- Topiramate
- Perampanel
- Nelfinavir
- Ritonavir
- Efavirenz
- Nevirapine
- Aprepitant
- Bosentan
- Modafinil
- St John's Wort

Stockley's reports that "St John's wort may slightly reduce the levels of desogestrel, ethinylestradiol, and norethisterone…" Both breakthrough bleeding and, rarely, contraceptive failure have been reported in women also taking St John's wort. Stockley's advises that women taking oral hormonal contraceptives should generally avoid St John's wort.

6. Contraindications and precautions

Our previous application provided detail on contraindications and precautions (p19), and these are also available in the WHO MEC document, see: http://whqlibdoc.who.int/publications/2010/9789241563888_eng.pdf.

As the Medicines Classification Committee wanted to see further consultation with healthcare providers, we have consulted not only with an expert on family planning in New Zealand, but also with GPs, nurses and obstetrician and gynaecologist consultants in New Zealand and overseas. As a result of this consultation we have modified the screening tool based on their feedback. We expect to meet with medical organisations shortly.

We will be taking a cautious approach and referring women to their GP or the Family Planning Clinic where a contraindication is apparent or possible. We have used the WHO Medical Eligibility Criteria for contraceptive use (4th Edition 2010) as a basis for our screening tool. Different conditions are given four categories as follows in Table 1. Category 1 covers conditions for which there is no restriction for that contraceptive method. Category 2 covers conditions where the advantages of using the method generally outweigh the theoretical or proven risks. The WHO document is attached.

Table 1 WHO categories for contraceptive use in different circumstances

Category	With clinical judgement	With limited clinical judgement
1	Use method in any circumstances	**Yes** **(use the method)**
2	Generally use the method	
3	Use of method not usually recommended unless other more appropriate methods are not available or not acceptable	**No** **(Do not use the method)**
4	Method not to be used	

The draft screening tool (attached) allows use in all situations considered to be category 1 and some category 2 situations. In all category 3 and 4 and some category 2 situations patients are referred to the doctor. Provision through pharmacists in the US are in category 1 and 2 situations (see the document attached).

Table 2 lists all contraindications (category 3 or 4) for the COC and POP from the WHO MEC.[20] For category 1 and 2 conditions see the WHO MEC document at the link previously provided.

Table 2 Category 3 or 4 conditions for the COC and the POP from the WHO MEC

COC	POP
Postpartum non-breastfeeding <21 days Breastfeeding < 6 months postpartum Postpartum non-breastfeeding ≥ with other risk factors for VTE Age ≥ 35 years and smoking Multiple risk factors for arterial cardiovascular disease Controlled hypertension Elevated blood pressure levels (systolic ≥ 140 mm Hg or diastolic ≥ 90 mm Hg) Vascular disease History of or acute DVT/PE Known thrombogenic mutations Current or history of ischaemic heart disease or stroke Known hyperlipidaemias in certain cases Complicated valvular heart disease Major surgery with prolonged immobilisation Systemic lupus erythematosus in certain circumstances Migraine with aura (any age) Migraine without aura ≥ 35 years Breast cancer current or history Diabetes in certain circumstances Gall bladder disease in certain circumstances History of COC-related cholestatis Acute or flare viral hepatitis Severe cirrhosis Hepatocellular adenoma Malignant hepatoma Ritonavir-boosted protease inhibitors Certain anticonvulsants Rifampicin or rifabutin	< 6 weeks postpartum and breastfeeding Acute DVT/PE Current and history of ischaemic heart disease or stroke Systemic lupus erythematosus in certain circumstances Migraine in certain circumstances Current or past breast cancer Severe cirrhosis Hepatocellular adenoma Malignant hepatoma Ritonavir-boosted protease inhibitors Certain anticonvulsants Rifampicin or rifabutin

7. Possible resistance

Not applicable.

8. Adverse events - nature, frequency etc.

For most healthy women of reproductive age, the benefits of oral contraceptives will outweigh the risks. A prospective cohort study in the UK following 46,000 women for up to 39 years found a lower death rate in oral contraceptives users than non-users (relative risk 0.88 95% CI 0.82-0.93).[23]

The Medicines Classification Committee considered that "the risk-benefit profile of the medicines in this application was similar to other restricted medicines."[15]

VTE is a rare but important adverse effect of the COC. VTE usually involves a blood clot in the deep veins of the legs or pelvis. If the clot breaks free it can cause a pulmonary embolism (PE), so patients should be warned about symptoms of DVT and PE and advised to see a doctor promptly. The screening tool will look for risk factors for VTE. The information sheet for the COC provides details of symptoms and what to do if it occurs.

New Zealand data from Suspected Medicine Adverse Reaction Search (SMARS)

The SMARS database from 1 January 2000 until late 2013 for ethinylestradiol lists 54 reports of pulmonary embolism, and 67 reports of vascular adverse events, including 54 reports of deep vein thrombosis. The summary report for this medicine notes 278 reports in total including 2 deaths. Many of these reports were in combination with cyproterone (which is not being considered for reclassification).

For levonorgestrel, there are 349 reports, no deaths, and 30 reports of vascular adverse events, including 15 reports of deep vein thrombosis. Norethisterone had 34 reports, no deaths, 10 reports of DVTs and 4 of pulmonary embolisms. Desogestrel includes 25 reports in total and 1 death. There were 8 pulmonary embolism and 10 deep vein thrombosis reports.

In comparison, for cyproterone (which is not being considered for reclassification), there were 116 reports, 23 pulmonary embolisms, 24 vascular disorders, and 3 deaths. Most reports were for the cyproterone-ethinylestradiol combination.

Further information is available from the SMARS report in the appendix.

Cardiovascular disease and stroke risk

Atherosclerosis does not increase with oral contraceptive use. The risk of myocardial infarction (MI) instead arises from thrombosis, and was seen particularly in older users of higher dose estrogen-containing COCs in whom other risk factors cause arterial narrowing, e.g. smoking.[38] Use of COCs – either current or previous use – does not appear to increase the risk of an MI in nonsmokers. Risk factors for cardiovascular disease and stroke, including migraine, are screened for.

Breast cancer risk

Evidence around breast cancer is conflicting.[38] A large meta-analysis from 1996 found an increased risk (relative risk 1.24) which declined over time after discontinuing the oral contraceptive. Other large studies (e.g. Marchbanks, et al. and Milne, et al.) found no increased risk. The risk of death from breast cancer was lower in women who had ever used the oral contraceptive than never users (but this was not significant) in the large UK Royal College of General Practitioners' cohort study.[23] If there is any additional risk, it is small, disappears over time,[38] and the UK College of General Practitioners' cohort study suggests it is outweighed by the reductions in other cancers. [23]

Other effects

Oral contraceptives do not cause permanent infertility, but delay in conception after discontinuing the oral contraceptive is common. [38]

Changing in bleeding patterns, including breakthrough bleeding and amenorrhoea can occur with the POP, although neither are an important health concern.[38]

9. Potential for abuse or misuse.

The oral contraceptive is not addictive and would not be abused.

As for potential supply through a GP or family planning, a woman could lie about her medical history or age in order to gain supply. Information would be provided within the consultation and in a written leaflet to also highlight when not to use the medicine.

10. Further information

International experience with non-prescription supplies of oral contraceptives

Women in many countries around the world have non-prescription access to oral contraceptives.[16]

Experience from the United States and United Kingdom was provided in detail in the last application (p25-28). In the US, a collaborative care system has allowed pharmacists to supply specified prescription medicines under a protocol (which may be maintaining a supply or initiating it) as agreed with a doctor.[39] In the State of Washington, an estimated 4 million supplies of prescription medicines, including hormonal contraceptives, have been supplied by pharmacists under collaborative practice agreements, and there has not been a single legal case taken against a pharmacist or doctor from such supply.[7]

The state of California has, in essence, switched this medicine. Women will shortly be able to access hormonal contraception through the pharmacist without requiring a prescription or a collaborative agreement in place. This legislation was passed around a year ago, and the service is close to being ready, but it was delayed as part of a larger scope change.[40] Under this model, the patient completes a self-screening form which the pharmacist then considers

in light of WHO MEC information particularly, and decides on supply. There will be a requirement for about one hour of additional training (owing to prior learning in the area), and pharmacists can continue supply or initiate supply.

In Canada, pharmacists in all states can continue supply of medicines after assessment based on their professional experience.[41] This started in one state in 2007, and has since spread to all states. The pharmacist receives funding for their time. Some provinces require that the patient returns to the doctor within two years, but others leave it up to professional judgement. While the uptake has been low relative to doctor prescribing (pharmacists taking a cautious approach initially), pharmacist extension of supply is still in the hundreds of thousands of prescriptions in one state alone. In Quebec it is expected that from 1 April the pharmacist will be able to prescribe the oral contraceptive (including initiation). The family doctor is informed of the supply.

Three published studies in Western countries are of particular interest.

1. United States - The direct access study

In 2003-2005, 26 pharmacists in eight pharmacies with high emergency contraception use in the wider Seattle area in the US were recruited into the Direct Access study.[4] Pharmacists underwent 12 hours of training and supplied oral contraception in a collaborative care model, according to WHO level 1 criteria for patient safety. Blood pressure was taken by these pharmacists or specially trained pharmacy technicians. Women aged 18-44 years in need of contraception were eligible. Women filled out a self-screening form of 20 yes/no questions, presented this to the pharmacy and went through measurement of weight and blood pressure and completed a birth control history form. If there was any doubt about pregnancy, the woman bought and used a urine pregnancy test. Women could receive up to 12 months of hormonal contraceptives. During the study 195 women received hormonal contraceptives from a pharmacist without a prescription. High blood pressure, and BMI were main reasons for non-supply. Sixty per cent of women cited convenience as their primary motivator for pharmacy supply. The continuation rate of hormonal contraceptives at 12 months was 70% of those responding to the 12-month interview (but only 65% of women starting the study responded to this interview). Almost all respondents at the one-month interview were satisfied or very satisfied with the pharmacist-supply (98%), felt they could ask the pharmacist any questions (97%), would recommend the pharmacist to a friend (97%) and found it very convenient or convenient to get their supply from the pharmacist (98%). During the one-year study, nearly 40% contacted another health care provider.

Pharmacists were confident and comfortable with this role with contraception.

An early learning curve was described. In seven cases (3.5%) hormonal contraceptives were supplied outside of the protocol – elevated blood pressure at the initial or 3-month visit (n=5) and contraindicated concomitant medicines (n=2). Most were recent or current users of

hormonal contraceptives at time of initiation, which may have given the pharmacist confidence in the supply. These cases were caught during the doctor check on the forms. The study authors recommended that such a check be used, particularly at initiation of the service. Pharmacists in NZ are used to the model of care with training and supply with a screening form, and have taken their roles seriously. We note that the US study used a reference sheet of absolute contraindications to supply, whereas we have provided clear indications of when not to supply and parameters for supply throughout the forms to maximise clarity and minimise potential error. Additionally, in the US study, there was a lot of additional work around enrolling the patient in the study, which may have distracted slightly from the task at hand. We expect the training will be clear that no supply outside of the screening tool is permissible, even in the case of previous or current use under a medical practitioner.

A validation sub-study in the Direct Access study compared a consumer self-reported questionnaire and medical evaluation questionnaire completed by each participant's health care provider.[4] Both questionnaires were completed on the same day. Agreement between these questionnaires occurred in 392 of 399 comparisons. Where disagreements occurred, women were more likely to identify contraindications than their providers.

2. United States - Californian continuation of depot medroxyprogesterone

In a California study from 2003-2005, 27 pharmacists in community pharmacies partnered with 19 clinics to allow established users of depot medroxyprogesterone acetate to get reinjection from their regular clinic or a participating pharmacy.[42] Pharmacists who were trained in injection technique underwent training in contraceptive management. Sixty nine women received 143 injections in the demonstration project. One of the more frequently used pharmacists for this service reported on a collaborative approach with the nearby medical clinic:

"Cohen mentioned how valuable it was to work in collaboration with the clinic staff in the event a patient expressed a need to obtain additional clinical services, such as sexually transmitted infection testing."

A second pharmacist involved in this project also administered around 400 depot medroxyprogesterone injections over a four-year period outside of this demonstration project. Local doctors did not want to stock the product, and wanted to save time for patients of having to collect the product and return for the injection.

The doctors at clinics participating in the project *"…agreed that offering the pharmacy option helped to ensure patient's ongoing persistence with their contraceptive method."* However, some doctors considered that doctors or the clinic should be the sole provider of patient injections, with concerns about loss of income and patients forgetting to get their reinjections on time. Doctors who were supportive wanted all their local pharmacies to provide it for access reasons.

3. United Kingdom - Southwark and Lambeth study

A pilot study was conducted in five pharmacies in London to widen access to contraception in response to needs expressed by ECP service users.[43] Pharmacists (two per pharmacy) were trained through an MSc module at King's College London in Oral Hormonal Contraceptive Services. COCs and POPs were provided using a patient group direction (PGD). Evaluation of 21 months of contraceptive consultations was reported with key findings:

- Pharmacists adhered to the PGD, made appropriate referrals, and provided a *"high quality contraceptive service"*.
- 97% satisfaction with the service from service users who valued the service highly, particularly the convenience, anonymity, drop-in system, long opening hours and lack of waiting time.
- Mystery shoppers were overall satisfied
- 741 contraceptive consultations
- 512 consultations provided an initial supply of oral contraception, 46% of which were to women who had not previously used the oral contraceptive
- 181 consultations were for subsequent supplies – the main reason given for this being lower than the initial supply is because the client has returned to using ECP or condoms, largely because they do not have a regular partner, had moved from the area, or thought they had side effects from the pill
- 36 consultations resulted in a medical referral
- three consultations resulted in a referral for a person under 16 years
- 66% of consultations were with women under 25 years
- 45% of consultations occurred with ECP supply, 40% of consultations occurred after client request, 12.5% arose from referral from general practice, other pharmacies and sexual health clinics, and 2% arose from a conversation with the pharmacist (not ECP related)
- The pharmacy with the most contraception consultations had a significant drop in provision of ECP in the year after the oral contraception was introduced
- Supplies took on average 20-21 minutes for the initial supply (first-time or established user), 17 minutes for a subsequent supply, and 11-15 minutes for the various referrals
- In a three month period in 2011, nine pharmacies referred 29 EC users into LARC services, although none had attended for LARC by a month after the three month period ended. The report noted: "this result suggests the importance of maximising on any opportunity to provide service users with contraception 'on the spot'".
- A sub-study evaluating why 269 ECP service users did not want a contraceptive consultation found the top reasons were because the client: was already using oral contraception; was still considering oral contraception or LARC; was concerned about weight gain, fertility or other side effects; preferred condoms; or has an appointment elsewhere for oral contraception or LARC.

Recommendations from the pilot included:

- Consider expanding the service
- Reconsider the training
- Consider providing the service to women under 16 years where appropriate
- Further work to improve patient pathways, signposting and referrals between all contraceptive services
- Develop training at a national level in enhanced contraceptive counselling skills for all pharmacists to maximise opportunities to talk to young women about their contraceptive needs

From the above examples of women receiving pharmacist-supply of contraceptives, and from feedback from local and international experts, the message to maximise patient safety and integrated care is to ensure only trained pharmacists undertake these supplies, to include counselling in the training, to provide good clear guidance to pharmacists, and written information to the patient, and to audit consultation forms for each pharmacist within a short time of the consultation when they start to provide the service.

We suggest that pharmacists have each of their first 10 consultations audited within five days of providing oral contraception, as part of their training process. We note that the pharmacists will have already had to pass a test, will be working within a clear screening form, have almost certainly already been trained to provide emergency contraceptive pills and trimethoprim (so have recently had information on STIs). Furthermore, as a comparison, vaccination assessment is with two injections, and pharmacists have shown they are very capable of going through the process with the screening tool and injection. Prompt feedback would be provided should a deviation occur.

We will be clear about the expectation that consultations will be around 20 minutes long,[3] and require a private area, so that pharmacists will decide whether or not that will be workable in their practice before committing to training.

Other self-screening/pharmacy screening

A Mexican study in the 1980s found similar health profiles between women screened for pill use, women examined for pill use by doctors, and women receiving oral contraceptives with no medical supervision.[44] The authors noted that the women in the study, despite having generally low education, were well informed about their own health status.

A study in El Paso found that women could ascertain contraindications to the POP similarly well to nurse practitioners when women self-screened and a nurse practitioner screened on the same day.[45] Only 0.4% of women did not identify a contraindication which the nurse did. A further 0.6% of women considered they had a contraindication when it was not in fact a contraindication.

BP monitoring

We have included blood pressure checks and clearly stated referral to the doctor is necessary for the COC with a BP at or above a systolic of 140 mmHg or diastolic of 90 mmHg, in line with WHO MEC criteria.[20] Although one submission suggested that the blood pressure limit be made lower, we are not aware of evidence that suggests this is necessary.

This can be viewed on page 31 of the previous application. Many pharmacies have been providing blood pressure measurements in the pharmacy on a frequent basis. These have led to referrals to GPs for medical assessment and initiation of medication or adjustment of medication. With the sildenafil reclassification, more pharmacies have upskilled themselves and purchased appropriate blood pressure monitors for use in their pharmacy. The Pharmacy Guild and Green Cross Health have each prepared a standard operating procedure for their members with input from the Heart Foundation.

Continuation of supply where contraindications are present

Women who have contraindications to either the COC or POP who have been prescribed the medicine and seek continued supply from pharmacy will need appropriate management. Studies have found contraindications in some women who have been prescribed the COC[46] or POP[4] by a doctor. While little New Zealand evidence exists, research examining VTE cases from 1996-2002 found 9.3% of women who experienced a VTE were on second or third-generation combined oral contraceptives despite a past history of VTE.[47] Thus, it is likely that some current users of the medicine presenting in pharmacy may appear to have contraindications to use. Hence, for the protection of the women being treated, we are screening both continuation supplies and initiation for contraindications. Should the woman appear to have a contraindication, the pharmacist would attempt to contact the prescriber, and if this is not possible, would refer the woman back to her doctor, with documentation, noting that she is outside the pharmacist-supply criteria. Should the woman have run out of the medicine and her doctor not be accessible, Pharmacy Defence Advice (supported by RANZCOG) is that the pharmacist would be expected to recommend condom use or abstinence. The training will include this scenario, and we will suggest that written guidance be provided for pharmacists in their kit of information.

We anticipate that the POP would be used primarily where specially indicated, e.g. breast-feeding, continuation of previous supply from a doctor, or use where contraindications to the COC are seen. Patients would be advised of the small window for taking these tablets each day.

Failure and compliance

Although in theory pregnancy should only occur in 0.3% of women taking oral contraceptives, in real-life pregnancy occurs more often.[20] Therefore, to maximise quality of advice for women and minimise risk of early discontinuation or compliance problems, pharmacist

training will include information about advice to give, compliance matters and addressing fears the woman might have about the contraceptive. For women's benefit, pharmacists will have a consultation form to prompt on advice to give, to ensure all aspects are covered, and written information will be provided.

Cervical cancer smear tests

The World Health Organisation states that screening for cervical cancer and STIs *"…should not be seen as prerequisites for the acceptance and use of family planning methods when they are not necessary to establish eligibility for the use or continuation of a particular method."*[20] The American College of Obstetricians and Gynecologists Committee on Gynecologic Practice supported the reclassification of oral contraceptives, noting that *"cervical cancer screening or sexually transmitted infection (STI) screening is not required for initiating OC use, and should not be used as barriers to access."*[5] Women who are not currently taking the oral contraceptive will often still be at risk of cervical cancer, so strategies other than getting a smear when a woman gets her contraceptive are already needed. Women using LARCs may have five years before attending for contraceptive needs. It would be inappropriate to withhold LARCs using oral contraception instead to ensure return for a cervical smear test. It should therefore also be inappropriate to stop a medicine that has a side effect profile compatible with non-prescription supply being available in that way because of an unrelated test.

Please see the previous application for more detail on this area if required. Again found on page 33.

Sexually Transmitted Infections (STIs)

Sexually transmitted infections such as chlamydia are an important concern, particularly for young patients. Pharmacists are already referring women and men who may have symptoms or appear to be at risk of STIs to doctors. This will continue, including discussion of STIs during the supply of the oral contraceptive.

A precedent exists with the reclassification of the ECP in New Zealand and most developed countries. Pharmacists will receive training on STIs in their training and be given the NZSHS Guidelines for their folder of information. Screening and advice (verbal and written) with provision of the COC and POP will include STI risk factors and referral if necessary. Even without the certainty of supply through especially trained pharmacists, the American Committee on Obstetrics and Gynecology considered reclassification appropriate noting that STI screening *"is not required for initiating OC use and should not be used as [a barrier] to access."*[5] In the US Border Contraceptive Access Study, women obtaining non-prescription oral contraceptives from Mexico reported high levels of having been screened for STIs. It was not as high as the clinic users in the study (72% versus 87%, respectively), but in our model proposed we note especially trained pharmacists will provide verbal and written information regarding STIs, with a prompt on the consultation sheet.

Long-acting Reversible Contraception

Long-acting reversible contraception methods (LARC) are an important option in contraception as they have a lower failure rate than the pill and the condom.[20] Therefore, women considering non-prescription supply of contraception will receive written and verbal information on this important topic, including the benefits and where to access. This means women will be referred to the doctor and family planning for LARC discussion, but can be supplied an oral contraceptive as an interim measure if they were prescribed an oral contraceptive in the past three years. Teenagers who decided to use Depo-Provera but could not receive it at that appointment took on average 104 days to get the appointment to have the injection, with 7% becoming pregnant in the interim.[48]

In the Southwark and Lambeth project of pharmacist-supply of contraception in London (see further detail below), despite pharmacists discussing LARC and referring for LARC, LARC had low uptake,[43] suggesting many women were not interested or had barriers to access other than lack of awareness.

The American College of Obstetricians and Gynecologists stated that *"…efforts to improve use of long-acting methods of contraception should not preclude efforts to increase access to other methods."*[5]

Confidentiality, privacy and sensitivity

Confidentiality is important. Pharmacists will provide oral contraception in pharmacies within a private area. More and more pharmacies have consultation rooms and with monitoring of INR, and providing vaccinations, the ECP, sildenafil and trimethoprim, some pharmacies have added a second consultation room, and even a third. There is a requirement under the Pharmacy Council Protocol for Sale or Supply of Pharmacist Only Medicines for Chronic Conditions to ensure privacy, so this is sufficiently managed.

Qualitative research from the US suggested that some women thought a clinic would offer more privacy than a pharmacy, but others thought a pharmacy would provide increased privacy and comfort over a clinic.[49] One quote from a young woman was as follows:

> *"I think it would be more comfortable for younger people because it would save them from being nervous, because if you go to a clinic everybody knows you're at a clinic. And you only go to a clinic for that kind of stuff like birth control or STDs and stuff like that."*

Pharmacists are used to discussing sensitive subjects such as the emergency contraceptive pill and erectile dysfunction, and being sensitive to the needs of the patient who may be embarrassed. Pharmacists can sensitively help patients to access other health providers when necessary.

Responsibility of the Pharmacist Pharmacy Council's Protocol for Sale or Supply of Pharmacist Only Medicines for Chronic Conditions

This document, sets out expectations of the pharmacist for supplying medicines such as oral contraceptives without prescription. Such requirements are extensive. The document is available at http://www.pharmacycouncil.org.nz/cms_show_download.php?id=212.

As registered health professionals, pharmacists have a Code of Ethics to adhere to, need to work within the Code of Rights under the Health and Disability Act, and can have complaints made to the Health and Disability Commissioner. The Pharmacy Council registers pharmacists and can take action if substandard behaviour is seen, which can include losing their registration.

Accuracy

Pharmacist under-graduate training, the special training they do for this reclassification, and use of the screening tool helps maximise the safety of supply. It has been suggested that pharmacists are likely to be more guideline-compliant than doctors.[50] Pharmacists will be systematically asking the questions that are necessary to decide on safe supply. If unsure, e.g. whether a migraine has an aura or not, they can refer to a doctor or provide the progestogen only pill to be safe. The screening tools have been provided according to WHO MEC, they are comprehensive, clearly indicate where supply must not occur, and have had input from experts.

Availability for queries

Being available for queries after supply is important. When pharmacist-supply of oral contraceptive occurs, we will recommend that pharmacists encourage the woman to ask if any questions, and phone, email or drop in with any questions they might have, providing a card with the pharmacy opening hours, phone number and email contact as well as the name of the pharmacist who they spoke with. Women will benefit from easy access to a health care professional who can answer such questions.

Young people

Young people particularly need sensitivity and assurance of confidentiality in dealing with them with contraception. Qualitative research in 138 women in the US found teenagers not wanting to tell their parents about their contraceptive use was a barrier to going to a clinic.[49] Young people are at higher risk of STIs, and this will be covered in the training for pharmacists, as well as in the advice part of the consultation sheet.

Young people also need an easily accessible walk-in service as is clear from meningococcal C vaccine in Northland earlier where uptake was low in adolescents until they worked with the walk in clinics and mobile clinics.[51]

The proposed minimum age for supply is 16 years, because other issues may arise for a younger population, for example sexual intercourse at a particularly young age may have coercion involved, the body is less mature, and 16 is the legal age for consent to sexual activity. Some could argue that a 15 year-old who requests oral contraception might be better served by supplying it in pharmacy than denying it (providing the rest of the criteria are met). Indeed, please see the newspaper clipping attached on pregnancies in young teenagers in Greymouth. However, condoms could be offered should an under 16 year-old request the POP or COC, and she would be referred to the doctor for ongoing contraception. Guidelines will include that pharmacists offering this service provide a list of local clinics addresses and telephone numbers, including the Family Planning Clinic, if applicable, to facilitate a young person getting further assistance. It is not expected that ID would be requested showing the age unless a pharmacist particularly suspected a girl was lying about being 16 years old. We are open to committee views on the minimum age for supply.

Delegated prescribing versus reclassification

While NZ will soon have a delegated prescribing authority, this appears to be more limited than the models of patient group direction in the UK and collaborative supply in the US. Delegated authority would require the patients to be under the care of the signatory doctor, and therefore does not help for travellers or people who have not got a GP as yet or whose GP does not have this set up. Collaborative supply and patient group direction do not have this limitation.

Reclassification to Prescription medicine except when provided by a Pharmacist who meets the necessary criteria supply would ensure women can access oral contraceptives from most pharmacies under a standardised model that ensures national consistency and best practice. Delegated authority is unlikely to be nationally consistent, and in many cases is unlikely to provide specific tools for supply to help best practice at the time of supply. Women will be limited in terms of the provider they can use. For example, should a practice nurse be able to write a prescription under delegated authority, this still won't be near the patient. For patient-centred care, reclassification is more useful as it will increase access through "walk-in" centres – pharmacies that a woman can access in many places – in a standardised and safe way.

Opportunistic screening, therapeutic relationship and fragmentation of care

Pharmacists will be discussing the need for smear examinations and need for STI checks, discussion of condom use if at risk of STIs, and will provide written information on both. Written information will also include the human papilloma virus (HPV) vaccine use.

Medical practices are increasingly using multiple doctors and having part-timer doctors, such that it may be a different doctor at every visit. Many women will shift area as they will be renting and changing jobs and locations. Women can go to student health to get contraceptives or to family planning, yet the access this provides clearly outweighs the need

to have a therapeutic relationship with a single provider. It would be inappropriate to deny wider access to contraceptives (or as others have put it, hold women hostage to needing to see a doctor for oral contraceptives) on the basis of opportunistic screening, mental health discussions, developing a therapeutic relationship, or fragmentation of care when barriers to access have been demonstrated and unplanned pregnancy is very common. We refer the reader to previous submissions available on the Medsafe website, in which experts in the area state that the need for access through the pharmacist outweighs the concern about fragmentation, opportunistic screening (particularly given the way this is being addressed), and the need to build a therapeutic relationship. There is no suggestion of restricting men to get condoms for their sexual health needs only from the doctor to build a therapeutic relationship and allow opportunistic screening, despite the fact that men are typically more reluctant to see the doctor than women, and have a higher suicide rate than women. Hard to reach members of the population may at least be able to have their important contraceptive needs met with wider access, which is better than no care (as noted by various submitters).

It has been noted that screening for family violence and/or abuse is important, and this has been passed onto the training organisation for their consideration. They will be providing the training in conjunction with an expert in the field who will be well-placed to make a recommendation around this, outside of the MCC process.

Cost of the service

It is anticipated that pharmacists will charge a consultation fee for the time involved in the consultation. This fee will vary by pharmacy. For some women it is likely to have lower charges if prescribed by a doctor or family planning, and it will be their choice as to whether the convenience of the supply through the pharmacy warrants an extra charge or not.

Concerns about the financial incentive for pharmacists to supply can be answered as follows. Firstly, many consumer supplies through the pharmacist will be repeat supplies that have been initiated elsewhere. The pharmacist is not going to change from a brand a patient is on already and happy with unless there is an advantage for the patient. Secondly, pharmacists are concerned about affordability for their patients. Pharmacists spend a lot of unpaid time swapping prescriptions written for expensive originator brands to generics to save the patient money. Pharmacists would earn more out of the part charge on the originator brand than the generic, but instead put more time into saving the patient money. Anecdotally pharmacists are acutely aware of the pressure costs places on the patient. This is evident with the increase in co-payment fees that has seen many patients throughout the country consider what they can afford to pay for. Pharmacists would have no reason to manage the supply of oral contraceptives any differently.

When oseltamivir was reclassified, many pharmacists were greatly over-stocked with short-dated oseltamivir from the previous season when many people ordered it owing to the “bird flu” scare. Yet, despite that, pharmacists refused sales that were inappropriate,[52] were rarely

proactive in suggesting supply, and supplied very modest amounts of the product to consumers.[53] Additionally, the cost was a barrier for some pharmacists in recommending oseltamivir.[54]

This is not to say that pharmacists won't be charging for their time providing a consultation as is the case with other healthcare providers. We are expecting a quality service and this requires payment to ensure a sustainable business model.

We need to remember the consumer in this application. A US blogger, Andrew Sullivan,[55] noted:

"Women can think for themselves and make decisions with their doctor and pharmacist about what drugs they want to take – and the evidence shows they are good at self-screening. In fact, it would actually increase the ability to mitigate and respond to unanticipated side effects, since changing tracks will no longer require a doctor's visit and getting a new prescription. Assuming that women won't or can't take responsibility for themselves to consult with a doctor unless required to by arbitrary government policy is absurd."

Initiation

Our earlier application sought initiation of the oral contraceptives in oral contraceptive-naïve users. This application does not. This carries a risk of efficacious contraception not being used in the interim before getting to the doctor, in women who have not had an oral contraceptive before. However, it is in line with advice from medical groups.

Pharmacists will be able to re-introduce an oral contraceptive after a gap which may be the same or different to the previously prescribed oral contraceptive. Pharmacists will receive training on what is needed for re-initiation.

Consulting

We have been very aware of collaborating with other medical providers in our model of care. This has included consultation with a local expert in family planning, obstetricians and gynaecologists, a senior practice nurse in primary care, a clinical nurse advisor, and GPs. We have consulted with medical groups. To help achieve integrated health, with patient consent, pharmacists will send documentation to the GP notifying them of the service provided, and will refer women to the GP where they are at higher risk of side effects with the COC or the POP, or where any particular health issues become apparent (e.g. elevated BP, concerns about STIs, insufficient smears). We have also included on the information sheets the need to advise any healthcare provider the woman may see that they are taking oral contraceptives We note that this level of collaboration is higher than that agreed on in the Californian model (see the appendices for further information).

Other

Not all pharmacies will offer this service. Like the emergency contraceptive pill, pharmacists refer patients to other providers in this case. Pharmacists can find the time for the consultation – they have to do this on a regular basis in pharmacy, and have staffing and prioritisation to accommodate this need.

In terms of quantity of training, pharmacists have considerable under-graduate training (4-year degree programme plus a one-year internship with examination) and have been supplying the emergency contraceptive pill (if accredited) since 2001. To become a vaccinator, they have to complete pre-reading and a work book then have a half day course and pass an exam. They are well used to using screening tools, and the screening tools used are comprehensive with referral notes at each question to maximise safety. For supply to women who have had the oral contraceptive prescribed in the last three years, there is no need to have screening tools audited. It is not done for vaccinations, trimethoprim, sildenafil or the emergency contraceptive pill.

Inefficiencies are not inconsiderable for women currently. Travelling time to their GP, restrictions to weekdays (or even only select weekdays) to see their GP, and waiting up to an hour for their booked consultation easily adds up to half a day off work. When women suddenly discover they are running out of their tablets (a common occurrence),13 scheduling a late notice appointment is difficult and may not be with their regular doctor anyway. Women will find pharmacies very accessible, particularly at short notice. Many areas have pharmacies open seven days a week and for extended hours, with convenient locations for consumers. Consumers do not require an appointment to see a pharmacist, and do not need to wait long. An Australian study of women on oral contraceptives and patients taking statins found that over a third of participants had run out of this medication in the past 12 months.9 Of those who ran out, over a third had temporarily stopped their medication until they could see their doctor. Oral contraceptive users were significantly more likely to run out of their medication than statin users, but no further data differentiating oral contraceptives and statins were provided. Notably oral contraceptive users were more likely to have full time jobs than statin users, which may have made it more difficult to see the doctor when running out of medication. Women's access to other providers can also be restricted as regional family planning clinics may have restricted opening hours e.g. two days per week.

The risks and benefits of this medicine lend itself to availability without a prescription. A woman will know better if she needs contraception than a healthcare provider will. And research shows she can do a very good job in screening for contraindications and precautions.[56-58] In our proposed model, a pharmacist who has received training in the area will further help ensure guideline-compliant supply.

In 2013, in a Sunday Star Times article, Dr Roke an expert in sexual health reportedly indicated that supply of oral contraceptives through trained and tested professionals such as

pharmacists was reasonable.12 She reportedly said that it would make little difference if a trained pharmacist, rather than a general practitioner consulted with the woman for a repeat prescription. Dr Roke was quoted as saying: “as long as there is some degree of consultation at the time, and the person has been checked for the safety of the pill and checked they know how to use it.” Pharmacists are already highly skilled in this area, having managed eight reclassifications of medicines in the past five years.

There may be other models for oral contraceptive supply or prescribing. These should not prevent a reclassification with an appropriate risk-benefit profile. Pharmacists remain highly accessible on more days of the week than a general practice and without requiring an appointment.

Summary

Oral contraceptives have a similar safety profile to other medicines that are available without prescription. They have clear risk factors that women have been able to self-screen for. Our model maximises safety for women - only women who have a low risk on comprehensive screening can obtain oral contraceptives without prescription. These low-risk women would be considered eligible for oral contraception by any other health provider.

We have greatly appreciated input on our model of supply from doctors, nurses, pharmacists, academics and others in New Zealand and overseas. We have tweaked the model following this consultation. The final consultation with medical organisations is about to occur and will be incorporated in final materials. We have proposed a model that is more conservative than supplies in Canada, the Netherlands and California.

Women have been able to receive oral contraceptives from the pharmacist under collaborative agreements in parts of the US. These supplies are not limited to the doctor’s patients, and include initiation as well as continuation. Research suggests high levels of pharmacist compliance with the protocol.[4]

While the COC has an increased risk of VTE, we are taking a very conservative approach in selecting the lowest risk COCs, screening women for risk factors, ensuring POPs are available as an alternative, and having a low threshold for referral. Furthermore, positive long-term effects for women include a strong and well-established protective effect on ovarian cancer.

Risks for women of missing smear tests and STI testing have been managed by appropriate training of the pharmacist and including this in verbal and written advice to patients. Medical opinion in the literature strongly supports unbundling STI checks and smear tests from oral contraceptive supplies. Pharmacists are already having conversations about STI checks with patients, and will be comfortable continuing to do so. Our consultation feedback has not required any change in our approach to this.

Risks of poor adherence and LARC options have been addressed through comprehensive training of the pharmacist, as well as verbal and written advice for the patient.

We believe that our model is even stronger following the consultation process we have undergone. This consultation process includes two New Zealand obstetrics and gynaecology consultants, GPs, a senior practice nurse working in the primary care sector, a clinical nurse advisor, pharmacists, and women. Our consultation is awaiting a final couple of appointments for completion and further information will be provided on the consultation process and outcomes.

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