GREEN CROSS HEALTH

PHARMA projects

Reclassification of Selected Oral Contraceptives

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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, 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 ECP from pharmacists in New Zealand, providing a model of care for our proposal now. Pharmacists must undergo specific training to supply the medicine, and typically use a checklist for supply.

In 2014, Green Cross Health Ltd (formerly known as Pharmacybrands) and Pharma Projects 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 application therefore includes the out-standing matters from the 2014 application to the Medicines Classification Committee, specifically questions about integrated care, collaboration, pharmacist training, and pharmacist management of the patient. Previously we consulted with the leading expert in this field in New Zealand, and also spoke to experts in the United States, and pharmacy organisations within New Zealand. Our further consultation includes general practitioners, obstetricians and gynaecologists, a senior primary care nurse and clinical nurse advisor. We have also sought GP feedback on our application as suggested by the committee. Our consultation with medical organisations will shortly be complete.

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.

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

3. Name of company/organisation/individual requesting reclassification

Green Cross Health Ltd and Pharma Projects 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 three months' supply at one consultation. At our application in 2014 we proposed six months' supply, but some doctors have suggested three months' supply instead allowing this to be an interim measure for some before getting LARCs, for example. We are happy to work with three months' supply.

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

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. 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 as for a prescription medicine, including directions for use
- 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

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 as discussed in the previous application (p6).

In California, new legislation effective from 1 January 2014 will allow 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. The protocol for supply is being finalised by pharmacy and medical organisations and was delayed by being part of other scope of practice changes.[16]

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

Countries in which oral contraceptives are legally available without prescription with screening required include South Africa, Vietnam, Malaysia and Jamaica.[17] 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.

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[18,19] 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 2104, 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:[20]

> ***"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.[21] 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 have run out of tablets
- 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)
- women presenting for the emergency contraceptive pill, who can be offered oral contraception to start immediately
- women who are not using effective contraception currently
- 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.[18]

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.[22] 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.[23]

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.[24] 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%).[23] 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.[25]

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.[26] 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.[27] 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,[28] 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.[29] 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.[30]

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,[31] and with

supply of oral contraceptives to women stating serious risk factors in the on-line screening.[32] 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,[21] 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.[21] 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.[33] Workforce New Zealand has suggested the health workforce needs to work at the top of their scopes of practice,[29] and supply of oral contraception by pharmacists who have undergone additional training fits this desire.

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. Our consultation with medical groups is awaiting their availability. 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).

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. Needs of different cultures with respect to conversations about contraception will be included in the training. We will seek to translate our information sheets into common non-English languages.

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**
2	Generally use the method	**(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.[21] 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).[24]

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.[34] 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.[34] 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.[24] If there is any additional risk, it is small, disappears over time,[34] and the UK College of General Practitioners' cohort study suggests it is outweighed by the reductions in other cancers. [24]

Other effects

Oral contraceptives do not cause permanent infertility, but delay in conception after discontinuing the oral contraceptive is common. [34]

Changing in bleeding patterns, including breakthrough bleeding and amenorrhoea can occur with the POP, although neither are an important health concern.[34]

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.[17]

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.[35] 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.[16] 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.[36] 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. These 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.

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.[37] 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.[38] 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.[39] 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.[40] 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.[21] 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[41] 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.[42] 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, 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 is that the pharmacist would be expected to recommend condom use or abstinence. The training will include this scenario, and written guidance will be provided for pharmacists in their kit of information.

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.[21] 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."*[21] 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.

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.[21] 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. 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.[43]

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,[38] 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

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. Olsen's pharmacy in Greymouth has just added a third consulting room to their pharmacy (see photo attached).

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. 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.[44]

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 pharmacist-only 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.

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 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 screening women for risk factors 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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