



PRACTICE GUIDELINES

Pharmacist-Supply of Selected Oral Contraceptives (SOCs)

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Objectives

These guidelines aim to support a pharmacist to safely and appropriately supply selected oral contraceptives (SOCs) to women who meet the specified eligibility criteria. The pharmacist-provision of SOCs aims to provide a timely and convenient option for women to obtain their usual SOC.

REGULATORY REQUIREMENTS

The Gazetted medicines classification authorises individual pharmacists to supply selected oral contraceptives to women without a prescription, providing specific criteria are met.¹ These guidelines provide a summary of the essential regulatory and professional practice information pharmacists must be aware of when supplying SOCs without a prescription. However other regulatory, ethical and practice requirements will also apply, as with any pharmacist or pharmacy service.

For further information regarding the legalisation, regulations, standards and codes of practice that apply to pharmacy and pharmacists, please refer to the Pharmacy Practice Handbook and/or the Pharmacist Code of Ethics. The [Pharmacy Council's](#) 'Protocol for the Sale and Supply of Pharmacist-Only Medicines for Chronic Conditions [POMCC]² also applies to the pharmacist supply of SOCs.

The minutes from the 57th Meeting of the Medicines Classification Committee (MCC) describe the range of criteria and considerations for pharmacist-supply of SOCs.³ These Guidelines and PSNZ's approved training programme reflect these criteria, in addition to the contraindications and precautions, and accepted best practice for the supply of SOCs.

Medicines Classification

The Gazetted classification for the SOCs permitted to be supplied by pharmacists includes the requirement for registered pharmacists to:

- meet the clinical and eligibility criteria of the Pharmacy Council and PSNZ approved training programme (of which these Guidelines are part of), and
- successfully complete the training programme, and
- provide no more than six month's supply of the SOC, and
- supply the SOC in the manufacturer's original pack.

The classification requirements are available from the [Medsafe](#) website.⁴

"Emergency Supply" of Medicines: Medicines Regulation 44(m)

If a woman is not eligible for the pharmacist supply of a SOC, the pharmacist must refer the woman to a medical practitioner / Family Planning for a prescription.

The pharmacist may consider an 'emergency supply' of the woman's OC utilising the authority granted by Medicines Regulation 44(m), to provide time for a medical appointment to be made. The regulatory and practice restrictions will apply to an emergency supply, including patient must have been prescribed the OC by NZ registered authorised prescriber within the last 9-months, (ie. is in a current prescription period). Pharmacists may only supply one 21 or 28 tablet strip of any of the OCs, as a practicable alternative to the usual 72-hour quantity restriction described in the regulation.

Emergency supply of a medicine is **not** permitted to travellers from overseas who have not had that medicine prescribed by a NZ registered authorised prescriber.

While the 'emergency supply' regulation may be used to permit the supply of an OC for women ineligible for the pharmacist supply of SOCs, pharmacists must carefully consider the relevant clinical risk factors and whether a medical referral would be more appropriate. An emergency supply of an OC should be viewed as a temporary supply to provide time to arrange an appointment with the woman's usual prescriber.

SOCs available for Pharmacist Supply

The selected oral contraceptives (SOCs) approved for pharmacist supply include:

Combined Oral Contraceptives (COCs)

- Ethinylestradiol (35 mcg or less) combined with Levonorgestrel or Norethisterone.

Progesterone Only Pills (POPs):

- Levonorgestrel, Norethisterone or Desogestrel alone.

COMBINED ORAL CONTRACEPTIVES (COCs)

Ethinylestradiol (in combination with levonorgestrel or norethisterone only)

Medicine Classification:

Prescription medicine except when supplied at a strength of 35 mcg or less in combination with either levonorgestrel or norethisterone for oral contraception to women who meet the clinical and eligibility criteria of the Pharmacy Council and the Pharmaceutical Society of New Zealand approved training programme on oral contraception when sold in the Medsafe approved manufacturer's original pack containing not more than six months' supply by a registered pharmacist who has successfully completed the approved training programme.

Permitted COC formulations and products (at August 2017). Please refer to the [NZ Formulary](#) for current information:

Levonorgestrel + ethinylestradiol tablet

ethinylestradiol 20 mcg + levonorgestrel 100 mcg

Ava 20 (28 tab, 84 tab)

Loette (28 tab, 84 tab)

Microgynon 20 (28 tab, 84 tab)

ethinylestradiol 30 mcg + levonorgestrel 150 mcg

Ava 30 (28 tab, 84 tab)

Levlen ED (28 tab, 84 tab)

Microgynon 30/30 ED (28 tab, 63 tab, 84tab)

Monofeme (28 tab, 84 tab)

Norethisterone + ethinylestradiol tablet

ethinylestradiol 35 mcg + norethisterone 500 mcg

Brevinor (63 tab)

Norimin (28 tab, 84 tab)

ethinylestradiol 35 mcg + norethisterone 1 mg

Brevinor-1 (28 tab, 63 tab, 84 tab)

PROGESTERONE ONLY PILLS (POPs)

Desogestrel

e.g. *Cerazette 75 mcg* (28 tabs, 84 tabs, 168 tabs)

Medicine Classification:

Prescription medicine except when supplied for oral contraception to women who meet the clinical and eligibility criteria of the Pharmacy Council and the Pharmaceutical Society of New Zealand approved training programme on oral contraception when sold in the Medsafe approved manufacturer's original pack containing not more than six months' supply by a registered pharmacist who has successfully completed the approved training programme.

Levonorgestrel

e.g. *Microlut 30 mcg* (84 tabs, 28 tabs)

(NB. Postinor-1 1.5mg is indicated for emergency contraception only)

Medicine Classifications:

Prescription medicine except when supplied for oral contraception to women who meet the clinical and eligibility criteria of the Pharmacy Council and the Pharmaceutical Society of New Zealand approved training programme on oral contraception when sold in the Medsafe approved manufacturer's original pack containing not more than six months' supply by a registered pharmacist who has successfully completed the approved training programme.

Prescription medicine 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;

Prescription medicine except when specified elsewhere in this Schedule.

Norethisterone

e.g. *Noriday 350 mcg* (84 tabs, 28 tabs)

Medicine Classification:

Classified as a prescription medicine except when supplied for oral contraception to women who meet the clinical and eligibility criteria of the Pharmacy Council and the Pharmaceutical Society of New Zealand approved training programme on oral contraception when sold in the Medsafe approved manufacturer's original pack containing not more than six months' supply by a registered pharmacist who has successfully completed the approved training programme.

SERVICE PROVISION AND PROFESSIONAL OBLIGATIONS

When supply of an SOC is requested by a woman, she should be informed that a consultation with the pharmacist will be required and this may take 10-15 minutes. As some sensitive questions may be asked, the use of a private consultation area should be available and offered. It should be explained that the consultation is required to determine whether the pharmacist would be permitted to supply the oral contraceptive safely and appropriately, or whether the woman would need to see her medical practitioner and obtain a prescription.

Privacy

Pharmacists must meet their obligations in relation to respecting and protecting the privacy of patients in the provision of medicines, including the associated patient counselling and documentation. These obligations are described in the Pharmacist Code of Ethics, Pharmacy Services Standards, Privacy Act, Health Information Privacy Code, and Code of Health and Disability Services Consumers' Rights.

The SOC consultation should take place in a private area where it cannot be overheard and interruptions are minimised. A discrete area such as a consultation room should be available to offer patients, particularly when performing tests or physical assessments such as blood pressure monitoring and measuring weight/height.

Informed, Person-Centred Care

It is important to ensure women requesting a SOC understand key information regarding risks and benefits, and how to use oral contraception safely and appropriately for optimal effect. This is also a requirement of professional and regulatory codes of practice. Women should be informed through verbal and appropriate written information about use of the SOC, precautions, and when to seek medical advice.

Face-to-face consultations are required when possible, unless due to disability or geographical isolation within New Zealand where this is impractical.

Pharmacists are not permitted to supply (export) SOC's overseas to women outside of New Zealand. Women from other countries presenting to a pharmacist in New Zealand, may be supplied an SOC if all other criteria for supply are met.

If a pharmacist or locum has not successfully completed the approved training to provide SOC's, and no approved pharmacists are available in the pharmacy, SOC's cannot be supplied unless pursuant to a prescription, or in accordance with the Emergency Supply provisions (see above). If a pharmacist is not approved to supply, they should assist in the continuity of care by referring to a nearby

alternative pharmacy, a medical practitioner, Family Planning or Sexual Health Clinic.

Documentation of Assessment and Supply

Recording the supply is a regulatory requirement when providing pharmacist-only medicines and those exempted from prescription medicine status. Accurately documenting a clinical assessment or consultation is also essential for recording what was discussed and the course of action taken.

To help ensure that the supply of SOC's is safe and appropriate, a comprehensive assessment is required prior to the initial supply of SOC. This must be **repeated annually**, or if the woman requests a supply from a different pharmacy. The assessment incorporates the eligibility criteria specified by the MCC, the regulatory requirements of the medicines classification, and the UK Faculty of Sexual and Reproductive Healthcare (FSRH) Medical Eligibility Criteria for Contraceptive Use (UK MEC) 2016.⁵

An approved checklist/assessment tool for the Supply of Selected Oral Contraceptives must be completed by the pharmacist and should be retained (either electronically or in hardcopy) as a patient record for the initial/annual SOC consultation, and to facilitate resupply.

Scanned, or electronic copies of the completed assessment tool stored as part of the woman's electronic record in the pharmacy dispensing software will meet Pharmacy Council requirements² for documenting supply. This can also enable secure and compact storage with easy retrieval when required. As these records contain personal health information, they are subject to the requirements of the Health Information Privacy Code⁶ including storage and retention.

GP Notification

Notifying the woman's medical practitioner of the supply of a SOC is **strongly recommended** to support the principles of integrated practice, and for the general practice record and/or shared care records to be kept current. Unless the woman chooses to opt out, pharmacists should inform her medical practitioner of the assessment and supply of the SOC as soon as practicable. The SOC Assessment Tool includes a medical practitioner notification form which can be printed/scanned and sent to the GP. The Society recommends pharmacists determine the preferred method for this communication with the medical practitioner.

Women should also be encouraged to see their medical practitioner, Family Planning or Sexual Health Clinic for maintaining regular women's health and sexual/reproductive health checks.

Quantity of Supply

Only a quantity sufficient for up to a maximum of 6 months' supply of SOC's may be provided to eligible women. Quantities smaller than a 6-month supply may be provided according to need, however SOC's must only be supplied in a manufacturers' original pack.

After previous assessment and initial supply of an SOC by a pharmacist, further resupply can be made

according to need and subject to a brief check of ongoing safety and appropriateness. Resupplies can be provided with the understanding that a full assessment for supply is required every 12 months, and SOC's can only be supplied by pharmacists if it has been prescribed by a medical practitioner in the previous 3 years.

ASSESSMENT GUIDE FOR THE PHARMACIST PROVISION OF SOC'S

Annual Comprehensive Assessment – Guidance Notes

The following information provides a guide for pharmacists when assessing the suitability for supplying an SOC.

These guidelines are adapted from information, and considers clinical guidance from: the *World Health Organisation Medical Eligibility Criteria (MEC)*⁷, the *Faculty of Sexual and Reproductive Healthcare (Royal College of the Obstetricians and Gynaecologists)*⁸, the *Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)*⁹, and accommodates the recommendations and requirements specified by the Medicines Classification Committee (MCC)³.

We encourage pharmacists to refer to these resources for further information and detail.

Background

In considering eligibility for the pharmacist-supply of an SOC, a medical practitioner has previously initiated the prescribing of the OC for the woman and it is the pharmacist's role to ascertain if it is safe and appropriate to resupply the OC without a prescription. The pharmacist is responsible for assessing if there have been any changes to the health status of the woman, or that of her close relatives, which may lead to an increased risk to the woman's health from using an SOC.

In making their recommendation to reclassify, the Medicines Classification Committee (MCC) considered submitted information referencing the UK Medical Eligibility Criteria for contraceptive use (UK MEC 2016) to guide pharmacist-supply of SOC's. The MEC document provides evidence and guidance for the risks and benefits of various contraceptive methods, and categorise this as⁵:

- **MEC Category 1** - Where there is no restriction for the use of the contraceptive method;

The Consultation

A face to face consultation is required for the initial pharmacist supply and the annual assessment where physiological parameters need to be measured. Consultations for the resupply of SOC's could be conducted via telephone or electronically if a woman is unable to return to the pharmacy; but only if the pharmacist is able to check compliance and

- **MEC Category 2** - Where the advantages of using the method generally outweigh the theoretical or proven risks;
- **MEC Category 3** - Where the theoretical or proven risks usually outweigh the advantages of using the method;
- **MEC Category 4** - Where there is an unacceptable health risk if the contraceptive method is used.

Pharmacists are authorised to supply SOC's in circumstances where there is good evidence to support the use, and the advantages of using the contraceptive generally outweigh any risks. However, pharmacists should have a low threshold for referring a woman for medical assessment if the potential risk to an individual is not clear.

The evidence supporting these safety categories is detailed in the [UK Medical Eligibility Criteria \(UKMEC\) 2016](#) document, and pharmacists are strongly encouraged to read and refer to this for further information.

any changes to the woman's health. Refer to the Pharmacy Council protocol for POMCC for further detail.

Pharmacists cannot supply the SOC to women outside New Zealand as e-mail and internet sales/export overseas are not permitted.

CHECKING ELIGIBILITY: IS THE WOMAN ELIGIBLE FOR SOC SUPPLY?

Current user of a permitted Combined Oral Contraceptive Pill (COC)

- Ethinylestradiol (35 mcg or less) combined with levonorgestrel or norethisterone.
- Aged between 16 and 39 years only

or

Current user of a permitted Progestogen Only Pill (POP)

- Levonorgestrel, Norethisterone or Desogestrel alone
- Aged between 16 and 52 years only

Pharmacists are only able to supply the permitted “selected oral contraceptives” (SOCs) and must supply the same formulation (active ingredients and/or dose strengths) as previously prescribed. However, supplying a different formulation or brand of SOC from what is usually taken is permitted if one of the following exemptions apply.

Switching between SOC formulations

Supplying a woman with an SOC that has a **different formulation** (active ingredients and/or dose strengths) from what she was previously prescribed, is only permitted when:

- **A woman from overseas has run out of her OC:** and her OC formulation is not available in New Zealand. The pharmacist may then switch to a formulation that is the most similar to the originally prescribed oral contraceptive;
- **A breastfeeding woman wanting post-partum contraception and who is a previous SOC user:** may be supplied a POP only once, in order to give them enough time to have a consultation with a medical practitioner to decide which form of ongoing contraception is best. (See example eligibility scenario below).

Switching between SOC brands

If the funded brand of an SOC changes (formulation / content of the active ingredients remains the same), pharmacists are permitted to supply either brand in consultation with the woman. For example, with the subsidised brand of one COC changing from *Monofeme* to *Ava30*, after discussing with the woman a pharmacist may supply either brand, as the overall content formulation is the same (ethinylestradiol 30 mcg + levonorgestrel).

If a woman’s prescribed brand is no longer available, pharmacists can offer an alternative brand that has the same combination and dose of active ingredient(s). For more information on the contraceptive brands available, refer to [section 7.3.1 of the New Zealand Formulary](#).

Non-permitted Oral Contraceptives may **not** be supplied

Only those oral contraceptives falling under the definition of the “selected oral contraceptives” are permitted to be supplied by pharmacists without a prescription. Women taking any COC that is **NOT** ethinylestradiol (35 mcg or less) combined with levonorgestrel or norethisterone; or is **NOT** a POP containing levonorgestrel, norethisterone or desogestrel alone, must be referred.

SOC **must** have been previously initiated by a medical practitioner

To be eligible for pharmacist supply, the woman must have had a SOC prescribed by a medical practitioner (in New Zealand or overseas) within the last 3 years. After first starting the SOC, the woman needs to have had at least one further appointment with a medical practitioner, to permit resupplies of the SOC by a pharmacist. This is to ensure use of the SOC has been medically reviewed post initiation.

Ideally, presentation of a previously dispensed and labelled SOC box would provide sufficient confirmation of what is currently taken. Verbal confirmation from the woman of the SOC used and that she has seen a doctor for a prescription for this SOC within the last 3-years is sufficient. Sighting copies of a previous SOC prescription or the computer prescription record are not necessarily required, and the last dispensing does not need to have been at the same pharmacy. However, the pharmacist **must be confident** that the SOC used is accurately identified before supplying. If the pharmacist cannot confidently confirm this information, the woman will need to be referred for a prescription.

If a woman is uncertain of the brand of OC being taken, the pharmacist may consider showing example packets or using tools such as the [Family Planning contraceptive flip-chart](#) to help identify the brand of SOC. Alternatively, consider phoning the prescriber or a previous pharmacy to confirm the OC formulation/brand, and/or for the date that the last prescription was written or dispensed.

Contraception indication only

The medicines classifications permit pharmacists to supply SOC for contraceptive purposes only. Pharmacists must determine if the OC was prescribed primarily for contraception, or for other indications such as acne, cycle control, etc. Women prescribed SOC primarily for indications other than contraception, must be referred to a medical practitioner. Note that many young women are initially prescribed the OC for non-contraceptive indications, but this may change on becoming sexually active. These women should be encouraged to see their medical practitioner for a sexual health check.

Example Eligibility Scenarios:

- **A New Zealand woman who will soon run out of her OC** - The pharmacist can complete an assessment to supply SOC, if safe and appropriate.
- **An overseas woman who will soon run out of her OC** - The pharmacist can complete a SOC assessment to supply SOC, if safe and appropriate. The pharmacist may supply the same SOC if this is available in New Zealand, or switch to a product with the same or *the most similar* formulation. Export supply of SOCs is not permitted.
- **A woman's usual OC is not within the defined ingredient/dose requirements for a "SOC"** (eg. Microgynon 50; or Mercilon/Marvelon, Yaz/Yasmin or Qlaira; or other active ingredients), the woman must be referred to a medical practitioner. Pharmacists are only permitted to supply the selected oral contraceptives (SOCs).
- **Woman collecting ECP and previous SOC user** - The pharmacist can complete a SOC assessment to supply SOC, if safe and appropriate. Referral to a medical practitioner is required if: the woman is under the age of 16, was last prescribed the SOC more than three years ago, has other sexual health concerns, or if alternative forms of contraception may be considered suitable (such as long-acting).
- **Woman wanting to restart contraception and previous SOC user** - The pharmacist can complete a full assessment to supply SOC, if safe and appropriate (and meets criteria for supply including prescribed in past 3 years).
- **Woman wanting post-partum contraception and previous SOC user:** see below

Special Considerations for Postpartum Oral Contraceptive Use

Combined hormonal contraceptives may disrupt the production of breast-milk, and increase the risk of thrombosis in a period of increased cardiovascular risk. Refer to the UKMEC 2016 for further information.⁵

If the woman is **not breastfeeding**, the pharmacist may supply the same SOC as before (COC or POP), or if this is not available, switch to an equivalent product with the same formulation.

If the woman **is breastfeeding** the pharmacist is **only able to supply a short supply of a POP** (i.e. 1 calendar pack strip), in order to give enough time for a consultation with a medical practitioner, Family Planning or Sexual Health Service.

The woman can then discuss the full range of contraception options with the prescriber (including injectable, implants, IUD) and decide the preferred/most suitable form of ongoing contraception.

Breastfeeding: previous COC or POP user

- Pharmacists are not authorised to supply COCs if the woman is breastfeeding.
- POP is the only type of SOC that a pharmacist may supply to a woman who is breastfeeding, regardless of the type of SOC that she was prescribed previously.
- Breastfeeding women can use POPs without restriction (MEC category 1).⁵ Normal "starting rules" apply before will be effective as contraception.
- When recommencing oral contraception post-partum, women must first see their usual prescriber to discuss available contraception options.
- Following the initial post-partum consultation with the prescriber, and if a POP was chosen as the preferred option of contraception, pharmacists are permitted to supply the POP. (However, it is likely a prescription would be provided at the time of consultation).
- If not breastfeeding – there are no restrictions and can start a POP immediately (MEC category 1).⁵

Not breastfeeding: previous COC user

- Pharmacists are not permitted to supply a COC to a woman who is up to 6 weeks (42 days) post-partum.
- For women up to 6-weeks (42 days) the postpartum period can present additional risks of thrombosis. These may include immobility, transfusion at delivery, high BMI, postpartum haemorrhage, post-caesarean delivery, or preeclampsia. The use of COCs may pose an additional increased risk for thrombosis, therefore such women must be referred.⁵
- After 6-weeks (42 days) postpartum, the usual SOC may be supplied if the woman is not breastfeeding. Normal "starting rules" apply before it will be effective as contraception.
- Breastfeeding women who are at least 6-months postpartum may use COCs, but this must be prescribed.

Refer to the UKMEC 2016 document for further information on the risks and benefits of COC and POP use in the postpartum period and breastfeeding.⁵

CHECKING CLINICAL RISK FOR CONTINUING OR RESTARTING SOC

Potentially Significant Adverse Events: Supply Inappropriate / Need to Stop OC

The following signs and symptoms are potentially serious adverse events which might suggest the development or risk of a blood clot or a cardiovascular event. Women should be advised to stop taking OC and to seek medical advice immediately if any of the following occur:

- Sudden severe chest pain (even if not radiating to left arm);
- Sudden breathlessness (or a cough with blood-stained sputum);
- Unexplained swelling or severe pain in calf of one leg;
- Severe stomach pain;
- Serious neurological effects including unusual severe, prolonged headache especially if first time or getting progressively worse or sudden partial or complete loss of vision or sudden disturbance of hearing or other perceptual disorders or dysphasia or bad fainting attack or collapse or first unexplained epileptic seizure or weakness, motor disturbances, very marked numbness suddenly affecting one side or one part of body;
- Blood pressure above systolic 160 mmHg or diastolic 95 mmHg;
- Prolonged immobility after surgery or leg injury.

Any of these symptoms could indicate potentially serious adverse events such as deep vein thrombosis (DVT), pulmonary embolism (PE), venous thromboembolism (VTE), myocardial infarction (MI), or stroke. Pharmacists need to counsel the women regarding what symptoms to be aware of and what action to take if they occur at any time while they are taking the OC.

Current Health Status

Pharmacists must assess the woman's current health status to determine the presence of any risks that may make resupply of the SOCs inappropriate, and/or potentially harmful to the woman's health.

Pregnancy is the most obvious significant contraindication for contraceptive use, if it is known that the woman is already pregnant. However, if pregnancy is unknown, and COC, POP or ECP are taken inadvertently during early pregnancy,

evidence does not show any increased risk of birth defects.¹⁰

- The pharmacist needs to determine if there is any chance the woman may already be pregnant - ask if she has missed any pills, or had a delayed/lighter than normal period.
- Any unprotected sexual intercourse (UPSI) within the last 7-days and missed pill? Consider appropriateness of the emergency contraceptive pill (ECP) if the UPSI was within the last 72 hours. If UPSI took place more than 72 hours previously, the woman will need to be referred to a medical practitioner for emergency contraception (ECP/IUD). Refer to PSNZ-PCNZ ECP Guidelines.
- Consider offering a pregnancy test prior to supplying SOCs. However, note that a human chorionic gonadotropin (HCG) test is only effective 2-weeks after UPSI (3-weeks since last period).

Pharmacists may need to use their professional judgement and discuss the benefits and risks and individual circumstances with the woman.

The woman should also be asked if she has any of the following changes in health, and if so she should be referred to a medical practitioner:

- Any unexplained vaginal bleeding? - possible symptom of an underlying medical condition that needs investigation⁷
- Is she less than 6-weeks post-partum? - increased risk of thrombus (see above)⁷
- Is she breastfeeding? - another form of contraceptive might be more appropriate (see above).
- Has she any new or worsening headaches, migraine with aura? - possible symptom of vascular changes.
- Any prolonged immobility or planning surgery or a long-distance flight? - increased thrombus risk
- Is she taking any contraindicated medicines - change in health status;
- Has she (or a close relative) recently been diagnosed with breast cancer, heart or kidney problems, epilepsy, or hypertension?
- Evidence is unclear about the relationship between OCs and depression. If a woman has experienced significant mood changes she should be referred to her medical practitioner.

Contraindicated Medical Conditions

The use of OCs is contraindicated with some medical conditions, where the risk of harm is increased by the use of hormonal contraception. Women with any of these contraindications should be referred.⁵

COC contraindications: Pregnancy, breastfeeding, history of breast cancer, liver or gall bladder disease, problems with blood circulation, high cholesterol or lipids, lupus, severe Crohn's disease, bariatric surgery, unexplained or abnormal vaginal bleeding, DVT/PE, migraine with aura, stroke, ischaemic heart disease, hypertension ($\geq 140/ >90$ mmHg), blood clotting or circulation disorders.

POP contraindications: Pregnancy, history of breast cancer, severe liver problems, lupus, severe Crohn's disease, or bariatric surgery, unexplained or abnormal vaginal bleeding.

Drug interactions / Contraindicated Medicines

It is not safe or appropriate to supply SOC to a woman who is taking any interacting or contraindicated medicines, and she should be referred to a medical practitioner for a prescription/medical assessment, or an alternative form of contraception.

The supply of SOC is contraindicated if the woman is taking:

- Any medicines which are treating a contraindicated medical condition
- A medicine which is known to induce drug metabolising enzymes that may affect SOC efficacy.
- A medicine whose efficacy may potentially be affected by concurrent SOC use.
- Any other medicine if concurrent use is otherwise contraindicated or presents unacceptable risk.

Pharmacists are expected to determine if any concurrently taken medicines present risk of a clinically significant interaction with the SOC. Standard recommended drug interaction references should be fully utilised to identify and determine this risk. The [New Zealand Formulary interaction checker](#) provides useful quick summary information on drug interactions, including advice on the severity of the interaction and recommends actions to be taken. Specialist references such as Stockley's Drug Interactions provide more detailed advice.

Supply of a **Combined Oral Contraceptive (COC)** is contraindicated if the woman is also taking medicines that may lower COC effectiveness, such as anti-epileptics, HIV medicines, St John's Wort, rifampicin, rifabutin or other CYP3A4 inducers.

Supply of a **Progestogen Only Pill (POP)** is contraindicated if the woman is also taking

medicines that may lower POP effectiveness, such as anti-epileptics, St John's Wort or CYP3A4 inducers.

Note that current evidence shows:

- Most broad-spectrum antibiotics do not affect the contraceptive effectiveness of COCs⁷.
- Studies of antifungal agents have shown no clinically significant pharmacokinetic interactions with COCs⁷.
- Studies of antiparasitic agents have shown no clinically significant pharmacokinetic interactions with COCs⁷.
- Rifampicin reduces the effectiveness of COCs and POPs. When a COC is chosen for ongoing contraception in women taking rifampicin, a preparation containing a minimum of 50 mcg ethinylestradiol should be used.¹¹ However, pharmacists are not permitted to supply SOC with more than 35mcg ethinylestradiol, and likewise cannot supply double doses (i.e. 60 mcg ethinylestradiol). Therefore, these women must be referred to their medical practitioner for a prescription or an alternative form of contraception.
- Use of certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine) may decrease the effectiveness of COCs and POPs⁷. Use of other contraceptives should be encouraged for women who are long-term users of any of these medications. When a COC is chosen, a preparation containing a minimum of 30 mcg of ethinylestradiol should be used⁷. Pharmacokinetic studies show levels of lamotrigine decrease significantly during COC use and increase significantly during the pill-free interval and some women experienced increased seizure activity⁷. No drug interactions have been reported among women with epilepsy taking lamotrigine and using POPs⁷.
- Antiretroviral agents have the potential to either decrease or increase the levels of steroid hormones in women using COC contraceptives. Pharmacokinetic studies suggest potential drug interactions between some antiretroviral drugs (particularly some non-nucleoside reverse transcriptase inhibitors and ritonavir-boosted protease inhibitors) and some hormonal contraceptives. These interactions may reduce the effectiveness of the hormonal contraceptive. POP are categorised as generally safe and effective⁷. Additional barrier methods of contraception are also required to prevent transmission of HIV⁷.

The UK Faculty of Sexual and Reproductive Healthcare (FSRH) have provided a dedicated [guideline on drug interactions](#) which is highly recommended.¹¹

Cardiovascular and Stroke Risk (COCs)

Pharmacists should use their professional judgement in determining the potential cardiovascular risks for an individual woman, and if continued supply of a COC is safe and appropriate. The risk factors for arterial cardiovascular disease includes:

- Age 35 years and over
- BMI 30-34.9kg/m²
- Smoking – current or within last year
- Cardiovascular disease - Raised cholesterol / hypertension
- Diabetes
- Migraine
- Heart disease in close male relative aged < 55 years old or female relative aged >65years old.

Is it safe to continue a COC?

Pharmacists should measure the woman's blood pressure (BP), and weight and height to calculate her Body Mass Index (BMI). The full (annual) consultation needs to be face-to-face for these measurements to be taken, however, re-supplies of a COC may be provided without the need to measure BP or BMI if a verbal consultation has excluded other changes in health status.

Diabetes

A personal history of diabetes is a contraindication for pharmacist supply of COCs.

COC use in women with diabetes, without vascular disease is generally considered safe (MEC category 2). However, with any vascular disease the risks become unacceptable and she should be referred to a medical practitioner to discuss alternative forms of contraception. POPs have little effect on diabetes control (e.g. HbA1c levels), haemostatic markers or lipid profile and are categorised as generally safe⁷.

Among women with insulin or noninsulin-dependent diabetes, COC use had limited effect on daily insulin requirements and no effect on long-term diabetes control (e.g. HbA1c levels) or progression to retinopathy⁷. Changes in lipid profile and haemostatic markers were limited, and most changes remained within normal values⁷.

Blood Pressure (BP)

Pharmacists should refer women to their medical practitioner, if the BP is outside the recommended safety range of:

- Systolic blood pressure is greater than or equal to 140mmHg, **or**
- Diastolic blood pressure is greater than or equal to 90 mmHg.

Among women with hypertension, COC users were at increased risk of stroke, acute myocardial infarction (MI), and peripheral arterial disease compared with non-users⁷. Discontinuation of OCs in women with hypertension may improve blood pressure control.⁵

An elevated BP is categorised as an unacceptable risk for COC use (MEC category 3/4 - risks outweigh benefits). Women who are diagnosed as hypertensive but have BP adequately treated for hypertension have a reduced risk of acute MI and stroke as compared with untreated women. However if a woman is being treated with antihypertensives pharmacists are not permitted to supply COCs.

If a woman has blood pressure above the recommended range, the risk of harm may outweigh the benefits of a COC and the woman should be referred to a medical practitioner to assess overall risk and/or consider if other contraceptive options may be more suitable.

Body Mass Index (BMI)

The greater the BMI, the greater the risk of thrombosis. Obese women who use COCs are more likely to experience thrombosis than obese women who do not use COCs. The absolute risk of thrombosis in healthy women of reproductive age is small⁷.

The UKMEC notes that the use of POPs is not restricted in women with an increased BMI, as they do not pose an increase in risk.

BMI 30-34 kg/m²

The UK MEC states that for women with a BMI between 30-34 kg/m² the benefits of COCs outweigh the risks of treatment/pregnancy. Pharmacists will need to consider the BMI in combination with other risk factors (see 'Cardiovascular Risk Precautions – when combined' section below).

BMI ≥ 35 kg/m²

For women with a BMI greater than 35 kg/m² the risks of COC use outweigh the benefits (MEC category 3) and should be referred to their medical practitioner as alternative forms of contraception may be more appropriate. Because of this increased risk, pharmacists are not permitted to supply COCs to women with a BMI greater than or equal to 35kg/m².

To calculate BMI, the woman's weight in kg and height in cm are required. BMI is weight (kg) divided by height in metres squared (m²) = BMI (kg/m²). There are a number of online BMI calculators (or apps) to choose from, for example:

- [Health Navigator](#)
- [The Heart Foundation](#)

Cardiovascular Risk Precautions – when combined

Some risk factors for use of the **Combined Oral Contraceptive (COC)** are less problematic if present on their own. However, when combined with one or more further risk factors, the combination presents an unacceptable overall cardiovascular risk. These include:

- Daily smoker current or in the last year
- Migraines without aura
- Known high cholesterol or other dyslipidaemia
- BMI = 30 - 34.9 kg/m²
- Heart disease/stroke in father/brother <55 years or mother/sister <65 years
- Age 35 – 39 years

When a woman has **more than one of these risk factors**, any of which alone would substantially increase the risk of cardiovascular disease, the use of SOCs may increase her risk to an unacceptable level⁵ and she should be referred to a medical practitioner to discuss other, more suitable, contraceptive options.

The presence of **only one** of these risk factors alone generally does not outweigh the benefits of COCs (MEC category 2)⁵ however the pharmacist under the reclassification process **cannot** directly supply the COC and the patient must be referred to their medical practitioner. Guidance from the UK supports the use of COC up to age 50 years if there are no medical contraindications to use.⁵ However pharmacists are only permitted to supply permitted COCs up to 39 years of age.

Smoking

COC users who smoke have an increased risk of cardiovascular disease (especially MI), compared with those who do not. The risk of MI increases with the number of cigarettes smoked per day⁷. POPs are categorised as safe to use in women who smoke, at any age.⁵

Migraine

Among women who have migraines, those who experience an “aura” have a higher risk of stroke than those without aura⁵. Women with a history of migraine (with or without aura) and who use COCs are about 2–4 times as likely to have an ischaemic stroke compared to non-COC users (who also have a history of migraine)⁷. The UKMEC categorise the risk of continuing COC in women who experience migraines

at any age (with or without aura) as unacceptable, however, the use of POP is unrestricted and generally safe.⁵

If a woman reports symptoms of migraine whilst taking a COC, she should be referred to a medical practitioner to discuss alternative contraception.

High cholesterol or other dyslipidaemia

Increased of total cholesterol, low-density lipoprotein (LDL) and triglycerides, or a decreased high-density lipoprotein (HDL), are known risk factors for cardiovascular disease. Women with known genetic lipid disorders are also at much higher lifetime risk for cardiovascular disease.

Family History of Heart Disease / Stroke

A family history of cardiovascular disease/thrombosis may present an increased risk for COC use. Pharmacists should consider the woman’s family history of cardiovascular risk/thrombosis and refer such women who take COCs to their medical practitioner or Family Planning. A medical assessment can identify the overall cardiovascular risk and consider alternative contraception options, if appropriate.

Age

The appropriate age range for the use of oral contraceptives is described in datasheets and guideline documents as from “menarche to menopause”. However, pharmacists are only permitted to supply SOCs to women from the age of **16 years to 39 years if taking a COC, or to 52 years if taking a POP.**

There are safety concerns regarding the use of COCs in older women as the risk of cardiovascular side-effects increases over the age of 35 years. Under medical supervision, in the absence of adverse clinical conditions (as listed above), COCs can be used until menopause⁷.

Requests for OC for women aged under 16 years of age must be referred to a medical practitioner. The use of oral contraceptives in women under the age of 16 is often for indications unrelated to contraception, such as the management of acne or to regulate the menstrual cycle. Also, the legal age of consent for sexual intercourse for women in New Zealand is 16 years. Therefore, it is more appropriate for ongoing supply to occur via prescription until the age of 16 has been attained.

APPROPRIATE USE – IS IT SAFE TO SUPPLY SOCS?

Professional Judgement

The pharmacist needs to apply their professional judgement as to whether the supply of SOC is safe and appropriate, or unnecessary or excessive to the patients' requirements [Pharmacy Council Code of Ethics obligation 6.13].

Pharmacists should consider:

- Is the SOC the most appropriate form of contraceptive for the woman?
- Could another form of contraception be more suitable or appropriate? E.g. if adherence is problematic, a long-acting reversible contraceptive (LARC) may be a better option.

Pharmacists are permitted to discuss any concerns, refer to, or consult with a medical practitioner having the care of a woman seeking an SOC, particularly if there is a potential risk to health.

If potential risks to health do exist, pharmacists are permitted and indeed should raise these with the woman's medical practitioner. Consent to contact is not necessarily required if there are concerns of a risk to her health. However if possible, pharmacists should discuss reasons for concerns with the woman, before discussing with another health practitioner.

COUNSELLING: INFORMATION AND ADVICE

Pill Teaching – Check the woman understands how to take the SOC

How to take SOCs

Pharmacists need to teach women how to take the SOC for optimal contraceptive effect. If taken as directed, the SOCs are very effective at preventing conception and have a failure rate of less than 0.3%. However, the actual failure rate is higher than this due to non-compliance i.e. missed tablets and UPSI.

Pharmacists should advise women on the importance of taking the COC or POP regularly, and the timing of administration, for it to work effectively. The key message is that good compliance (and following the 2/7-day rule) improves the effectiveness of SOCs at preventing an unwanted pregnancy.

'Tri-cycling' COCs is popular with some women as it reduces the frequency of menstrual periods and taking only hormone pills for 63 days (followed by a 7-day break) reduces the contraceptive failure rate from 7.3% to 4.4%¹². However, the process may need to be explained, and the 7-day rule is most important in the weeks either side of the hormone-free break.

Some women experience breakthrough bleeds when tri-cycling due to endometrium instability and they can take a break from the active hormone tablets for up to 7-days at this stage, menstruate, and resume taking the active tablets again.

Start by explaining that there are 3-ways to take the COC:

- 21 active hormone tablets then 7 inactive tablets (or a 7-day break) = Monthly menstruation;
- Continuous use of active hormone tablets only for 3 months then take 7 inactive tablets (or a 7-day break) = tri-monthly menstruation;
- Continuous use of active hormone tablets only for 2-3 months then up to 7 inactive tablets or up to a 7-day break when breakthrough bleeding occurs.

The POP is simpler to use, in that it is taken every day without a break.

Determine the time of day for taking the SOC.

- Identifying a routine and triggers (such as brushing teeth in the morning) increases the efficiency of pill taking;
- Be aware of challenges to this routine (a late sleep in at weekends might mean taking a POP is delayed by more than 3 hours and reduced efficacy);
- Mobile phone alarms and apps might be useful reminders and improve compliance.

Explain the structure of the COC packet

- Which tablets are active hormone tablets or inactive tablets;
- Where to start, how to follow the direction arrows;
- How to move to the next pack if missing out the inactive tablets.

Starting or Re-starting the COC after a break of more than 7-days

- If starting the COC during a menstrual period (days 1-5), start with an active pill and the contraception is effective immediately.
- If starting COC at any other time during the menstrual cycle, start with an active pill and abstain from sexual intercourse or use additional contraceptive precautions (eg. condoms) for 7-days. Contraceptive effect is not achieved until 7 COC pills have been taken in a row. If a condom breaks or there is unprotected sexual intercourse, emergency contraception will be needed.
- If switching COC brands, don't take a break between active hormone tablets.

Starting or Re-starting the POP after a break of more than 2-days

- If starting the POP during a menstrual period (days 1-5) then contraception is effective immediately;
- If starting the POP at any other time during the menstrual cycle, abstinence or additional contraceptive precautions (such as condoms) are required for 48 hours;
- Need to use condoms. If condom breaks or UPSI need emergency contraception.

Explaining the missed pill rules

- Demonstrate how to work out time from missed pills to restored contraceptive effect;
- Take the missed pill immediately, even if this means taking 2 together;

Missed COC:

- If ONE pill is missed (ie. >24h since last pill but <48h late): take missed pill AND that day's pill. Take rest of packet as usual. No additional contraception required.
- Use 7 Day Rule (use extra contraceptive precautions for 7 days) if: Missed TWO or more pills: in first week (after break/inactive pills), **OR** missed TWO or more pills in last week before taking break/inactive pills, **OR** if missed >8 pills in middle week (days 8-14);
- If vomit within 3 hours of taking pill – take another hormone pill.
- Vomiting/severe diarrhoea for more than 24-hours – follow the 7-day rule.

Missed POP:

- If > 3 hours late taking POP - take missed pill as soon as possible. Use 'Two Day Rule' (use extra contraceptive precautions for 2 days)
- If >12 hours late taking Cerazette® - take missed pill as soon as possible. Use 7-day rule. (UKMEC states 2-day rule for cervical mucus thickening effect, but 7 days to suppress ovulation)
- If vomit within 3-hours of taking pill – take another hormone pill.
- If condom breaks or UPSI during 'two day' or 'seven-day' rule timeframe - need emergency contraception.

Ask women to teach back the instructions

To help ensure that she understands how to take the SOC for optimal contraceptive effect.

A key message is for women to seek advice from a health professional if any event happens that may prevent the OC from working effectively. Prompt advice may enable precautions such as the emergency contraceptive pill to be taken, or an intrauterine device (IUD) to be fitted, to prevent an unwanted pregnancy.

Counselling: Is the woman reasonably informed?

Pharmacists need to explain to women how the OC works and how to take the OC to achieve the optimal contraceptive effect and good sexual health. The verbal counselling and any supporting written resources should include information regarding dosage, efficacy and adverse effects.

Pharmacists also need to discuss sexual health, including the risk of sexually transmitted infections (STIs) and the importance of regular sexual health screening, such as cervical screening.

Adverse Effects

Women should be counselled regarding the common, but minor, potential adverse effects to be aware of, when taking SOCs:

- COC side effects – nausea, breast tenderness, bleeds may change (e.g. become lighter or be irregular initially);
- POP side effects – irregular bleeds for first few months, bleeds may become lighter.

Women should also be counselled about the potentially serious adverse effects to be aware of as these could be a sign of a potential complication that needs to be checked by a health professional.

(See section: Potentially Significant Adverse Effects / Reasons to stop OC).

If a pharmacist cannot confidently determine whether the supply of a SOC to a woman would be safe and appropriate, OR if supply would be inappropriate, the pharmacist MUST refer the woman to a medical practitioner / Family Planning / Sexual Health Service.

SEXUAL HEALTH SCREENING

OCs do not protect against sexually transmitted infections (STIs), including Human Immunodeficiency Virus (HIV).

Pharmacists should provide advice and information regarding:

- Sexually transmitted infections: awareness, checks and protection depending on the woman's circumstances.
- Cervical cancer screening (smears): 3-yearly frequency from age of 20 years old.
- Human Papilloma Virus (HPV) and vaccine: free course of 3 injections.

Undiagnosed or untreated STIs can lead to serious complications (including infertility) and the need for more intensive treatment after diagnosis. Most STIs are asymptomatic in the earlier stages and as individuals may not be aware that they have an STI, everyone should be encouraged to have a regular sexual health check¹³.

The Centres for Disease Control and Prevention recommends that all sexually active women under the age of 25 years, as well as older women with risk factors such as new or multiple sex partners, or a sex partner who has a sexually transmitted infection should have annual STI checks.¹³ If there is a risk of STI, the correct and consistent use of condoms is appropriate. When used correctly and consistently,

condoms offer one of the most effective methods of protection against STIs⁷.

The common symptoms of sexually transmitted infections may include:

- Burning or pain when passing urine
- Lower abdominal pain
- Pain during or after sex
- Unusual vaginal discharge
- Irregular vaginal bleeding or spotting.

In addition to STIs, it is also recommended that women have cervical cancer screening (smears) every 3-years from age of 20 years old. In New Zealand, young women are able to access the Human Papilloma Virus (HPV) course of 3 injections. From 1 January 2017, HPV immunisation is free for everyone, male and female, aged 9 to 26, including non-residents under the age of 18. HPV vaccine protects young people from HPV infection and the risk of developing cervical cancer and a range of other HPV diseases later in life. For more information, refer to the Ministry of Health website and resources.

The pharmacist supply of oral contraceptives requires women to have a sexual health review with a medical practitioner, at least every 3 years, to ensure that it is safe and appropriate for pharmacists to resupply the OC in the interim.

RESOURCES SUPPORTING VERBAL AND WRITTEN INFORMATION

Provision of consumer medicine information leaflets and other printed information for consumers is required for the woman to take away with her and to support the verbal information provided.

Consumer medicines information is available in product packaging, via the NZ Formulary website, and other sources. However, The Society recommends use of the specific SOC consumer information developed by Green Cross Health and Natalie Gauld Ltd for the oral contraceptive

reclassification. This information should be provided to all women receiving a SOC from a pharmacist.

See also: The Ministry of Health's "[A compact guide to sexual health](#)". The [Family Planning website](#) also has patient information leaflets on COCs, POPs and STIs, and how to [locate the nearest clinic](#).

The Society recommends pharmacists have contact details of local sexual health and sexual assault service/rape crisis centres, readily available.

RESUPPLIES

Is it safe to resupply?

After the initial supply of an SOC, women are able to access further "resupplies" at the same pharmacy, without having to undergo a full assessment.

Between the annual pharmacist consultation and 3-yearly medical practitioner consultations, the SOC may be resupplied after a brief assessment, and if use continues to be safe and appropriate. The pharmacist must still check if there have been any issues with compliance, any relevant changes to health status, and/or if an STI check may be required.

Resupplies may be in 3-monthly or 6-monthly quantities, in accordance with the classification requirements. Recognising the requirement for an annual full assessment consultation. If the woman goes to a different pharmacy, a full assessment consultation is required.

A face-to-face assessment must be completed by a pharmacist annually, to continue the pharmacist supply of an SOC. All of the information collected at resupplies and the annual review must be recorded and added to the woman's electronic record.

Check Blood Pressure if Re-initiating

If the initial supply of an SOC was a re-initiation of hormonal contraception following an extended period without taking anything, blood pressure should be rechecked after 3 months. For example, restarting SOC use after giving birth > 12 months previous (and is not breastfeeding), and it is still less than 3 years since last seeing a medical practitioner. Rechecking blood pressure when resupplying can confirm restarting the SOC has not been untowardly affected.

Check Compliance

The follow-up consultation should identify any issues regarding the woman's compliance with the SOC. Questions could include:

- Has the medicine been taken regularly?
- Has she missed any pills in the past 3 months?
- Does the woman still require the medicine?
- If she has missed any pills recently, is there any chance that she may already be pregnant?
- Is SOC the most appropriate ongoing form of contraception?

If the pharmacist determines that the resupply of the SOC may no longer be appropriate for the woman or the woman wants to change the form of

contraceptive used then the woman must be referred to a medical practitioner / Family Planning.

Check Changes to Health Status

The follow-up consultation should identify any issues regarding any changes to the woman's health. Questions could include:

- Are there any changes in the person's health status since starting the medicine?
- Are there any symptoms experienced since the last consultation?
- Questions could include new or worsening headaches or changes in patterns of migraines?
- Questions could include new symptoms of cardiovascular disease?
- Have they commenced smoking?
- Have they (or close relative) recently been diagnosed with heart problems?
- Are they planning to undergo major surgery?
- Are they currently, or likely to be, immobilised (e.g. injury, long flight)?
- Are they pregnant or likely to be pregnant?

If at a follow-up consultation, it becomes apparent that the woman is ineligible for a repeat supply, the pharmacist must refer to the medical practitioner / Family Planning / Sexual Health Service.

Sexual Health Screening Check

The woman must be referred for a sexual health check-up with her medical practitioner / Family Planning / Sexual Health Service at least every 3 years for cervical smears, and STI checks more frequently if appropriate.

The follow-up consultation should include information to improve the woman's awareness of checks and protection depending on the woman's circumstances, regarding:

- Sexually transmitted infections.
- Cervical cancer screening (smears) – 3-yearly frequency from age of 20 years old.
- HPV – free course of 3 injections.

The common symptoms of sexually transmitted infections may include:

- Burning or pain when passing urine;
- Lower abdominal pain;
- Pain during or after sex;
- Unusual vaginal discharge;
- Irregular vaginal bleeding or spotting.

If a pharmacist cannot confidently determine whether the **RESUPPLY** of a SOC to a woman would be safe and appropriate, OR if supply would be inappropriate, the pharmacist **MUST** refer the woman to a medical practitioner / Family Planning / Sexual Health Service.

Useful Resources

[Ministry of Health HPV Immunisation Programme](#)

Information and links to resources around the NZ Human Papilloma Virus (HPV) immunisation programme.

[New Zealand Formulary](#)

Section 7.3 Contraceptives

[New Zealand Formulary interaction checker](#)

[UK FSRH Medical Eligibility Criteria for Contraceptive Use](#)

Compares the risks of using contraceptive methods with pre-existing medical conditions.

[WHO Medical Eligibility for Contraceptive use](#)

[Family Planning Patient Resources:](#)

Useful resources for pharmacists to discuss with women using the SOC service.

["A Compact Guide to Sexual Health"](#)

Consumer resource from the Ministry of Health HealthEd. Useful guide to discussion supporting sexual health.

BPAC "[How to guide for sexual health](#)"

From BPAC, produced by sexual health specialists to provide clinician-orientated guidance for sexual health consultations.

[Centres for Disease Control and Prevention](#)

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