Safer Care Victoria

VICTORIA State Government

October 2023

Protocol for Resupply of the Oral Contraceptive Pill

Victorian Community Pharmacist Statewide Pilot

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1. About

This Protocol has been developed to provide pharmacists authorised under the Drugs, Poisons and Controlled Substances Regulations 2017 (the Regulations) a clear framework to supply the Schedule 4 poisons documented in this Protocol for the purpose of resupply of the oral contraceptive pill (OCP) under a structured prescribing arrangement. It is a requirement of the Secretary Approval: Community Pharmacist Statewide Pilot that pharmacists comply with this Protocol when supplying Schedule 4 poisons for patients seeking the resupply of the OCP. It is also a requirement of the Secretary Approval: Community Pharmacist Statewide Pilot that pharmacists have completed the current training requirements specified in the departmental guidance before supplying Schedule 4 poisons.

It should be noted that the supply of the OCP under this Protocol is separate to and operates independently of Regulation 57 which allows for the supply of Schedule 4 poisons to a person without a prescription by pharmacists to allow continuity of treatment.

Pharmacists authorised to supply Schedule 4 poisons under the Regulations must:

- Operate at all times in accordance with the Drugs, Poisons and Controlled Substances Act 1981, the Regulations and all other applicable Victorian, Commonwealth and national laws.
- At all times act in a manner consistent with the Pharmacy Board of Australia's (the Board) Code of Conduct and in keeping with other professional guidelines and policies as set out by the Board as applicable.

Pharmacists are also expected to exercise professional judgment in adapting treatment guidelines to presenting circumstances.

1.1. DEFINITIONS AND ACRONYMS

BMI: Body mass index

COCP: Combined oral contraceptive pill

CST: Cervical screening test

DVT: Deep vein thrombosis

HCP: Healthcare practitioner

HPI-I: Healthcare Provider Identifier-Individual number

HPV: Human papillomavirus

LARC: Long-acting reversible contraception/contraceptive

MHR: My Health Record

OCP: Oral contraceptive pill

PCOS: Polycystic ovary syndrome

PE: Pulmonary embolism

POP: Progestogen only pill

RCOG: Royal College of Obstetricians and Gynaecologists

STI: Sexually transmitted infection

VTE: Venous thromboembolism

2. Protocol for Resupply of the Oral Contraceptive Pill

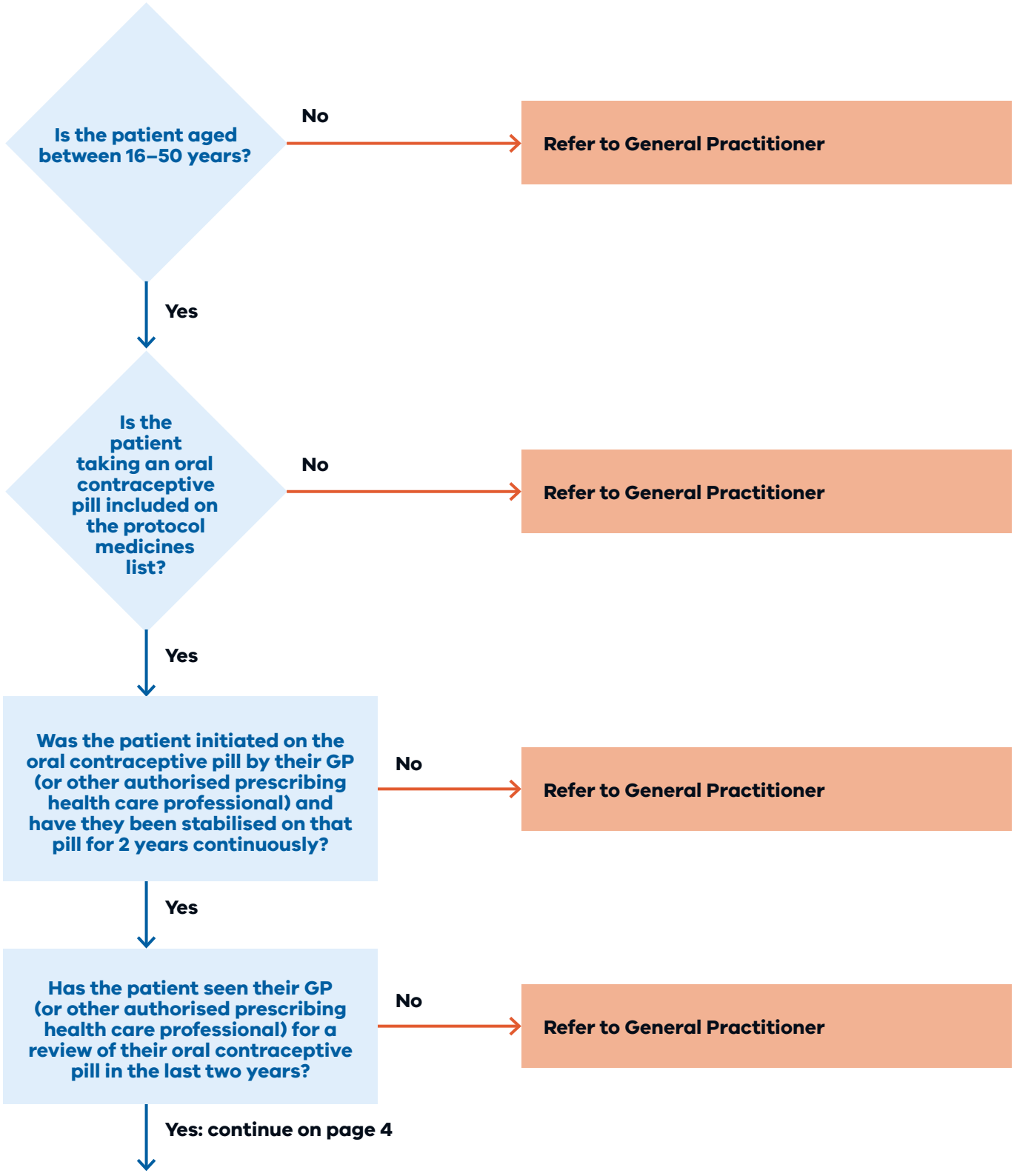
2.1. KEY TO COLOURS USED IN THIS PROTOCOL

Preliminary enquiries

Immediate referral

Pharmacist care and refer

Care provided by pharmacist



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Has the patient been continuously taking the oral contraceptive pill?

No → **Refer to General Practitioner**

Yes

Does the patient consent?*

No → **Refer to General Practitioner**

*The patient must be physically present in the pharmacy.

Yes

Assess patient needs to determine whether resupply is safe and appropriate:

- ☐ patient has previously been prescribed an OCP and received prescription from GP no more than 12 months ago (sight previous prescription, OCP pack or other physical and/or electronic dispensing records)
- ☐ review MHR, where possible/available
- ☐ provide reproductive health counselling, as needed
- ☐ check adherence and satisfaction with OCP, offer contraceptive counselling to explore other options as appropriate, e.g. LARCs

Resupply is not considered safe or appropriate → **Refer to General Practitioner**

Resupply is assessed as safe and appropriate:
continue to page 5

Continued from page 4

Conduct clinical review:

- ☐ measure BP +/- weight
- ☐ adverse effects to OCP
- ☐ changes in bleeding patterns
- ☐ changes in health that would be a contraindication to ongoing use - angina, heart attack, stroke/TIA, breast cancer, liver disease, DVT/PE, migraine with aura, new headaches
- ☐ new medications
- ☐ confirm OCP is still appropriate and meeting patient's needs, considering:
  - contraindications
  - drug interactions
  - pregnancy and lactation
  - potential pregnancy

Do any of the following apply?

- ☐ younger than 16 or over 50 years of age
- ☐ not currently taking and wants to restart
- ☐ request is for a different OCP or a different type of contraception, e.g. a LARC
- ☐ requested OCP is not on the protocol medicines list
- ☐ requested OCP is now contraindicated or not appropriate, eg hypertensive, BMI>35
- ☐ unexplained and un-investigated vaginal bleeding or acute, severe menstrual bleeding
- ☐ potentially pregnant
- ☐ STI screening is indicated (although OCP may still be resupplied by the pharmacist)

Yes → **Immediate referral to GP**

No: continue to page 6

Continued from page 5

If appropriate, prescribe per structured protocol and dispense OCP:

- provide one original pack (up to 4 months supply depending on product).
  Note: supply under the pilot protocol does NOT include supply provided under Regulation 57

Communicate agreed plan to resupply OCP:

- offer general advice about OCP as needed – patient resources/information, reminder of adverse effects
- provide copy of record of service to patient and patient's GP
- communicate with other health practitioners (if required)
- reminder that review by GP or nurse practitioner recommended to occur at least every 2 years.

Complete any other clinical documentation required for consultation.

3. Clinical documentation requirements

The pharmacist must make a clinical record of the consultation that contains:

- Sufficient information to identify the patient (Medicare number and date of birth are usually recorded when dispensing prescriptions)
- Date of treatment
- Name of the pharmacist who undertook the consultation and their Healthcare Provider Identifier-Individual (HPI-I) number
- Consent given by the patient regarding: pilot participation, costs, pharmacist communication with other healthcare practitioners (e.g. patient's usual treating GP) and access to the patient's My Health Record for the purpose of checking inclusion/exclusion criteria and uploading information relating to the consultation as required
- Any information known to the pharmacist that is relevant to the patient's treatment
- Any clinical opinion reached by the pharmacist
- Actions and management plan taken by the pharmacist
- Particulars of the OCP supplied to the patient
- Any referrals made to a medical practitioner or other healthcare professional
- Information or advice offered to the patient such as counselling on side effects, how to take and what to do in the event of missed pills.

The pharmacist must share a copy of the record of the service with the patient and with the patient's usual treating medical practitioner or medical practice, where the patient has one.

The pharmacist must make a record in the pharmacy software and an IT system approved by the Victorian Department of Health, regarding the supply.

Supplementary information

The supplementary information below provides additional guidance and information to Victorian pharmacists participating in the Community Pharmacist Statewide Pilot (the Pilot). It is intended to be used together with the guidelines and other resources referred to here to assist pharmacists in adhering to the management protocol and facilitate delivery of a safe and high quality OCP resupply service to the community.

4. Assess patient needs

An assessment of the person's needs must be undertaken to determine whether resupply of the OCP is safe and appropriate.

To determine whether resupply is safe and appropriate, pharmacists must understand the contraindications and precautions of the different OCPs. Pharmacists can find further information in the Therapeutic Guidelines and the current versions of the Royal College of Obstetricians and Gynaecologists (RCOG) Faculty of Sexual and Reproductive Healthcare (FSRH) documentation, including:

- UK Medical Eligibility Criteria for Contraceptive Use 2016 (UKMEC)
- FSRH Clinical Guideline: Progestogen-only Pills (August 2022, Amended July 2023)
- FSRH Clinical Guideline: Combined Hormonal Contraception (January 2019, Amended July 2023)

4.1. SEXUAL AND REPRODUCTIVE HEALTH COUNSELLING

Young people

- Patients under 16 years of age are to be confidentially referred to a general practitioner or sexual health clinic.
- Pharmacists should consider whether there may be child protection concerns relating to a request for contraception and report to Child Protection accordingly.

Women and gender diverse people over 50 years of age

- The choice of contraceptive should be reconsidered at age 50 and at menopause.
- Contraceptive use may be discontinued when the patient reaches 55 years of age, or earlier if menopause has occurred.
- Menopause may be assumed after one year of amenorrhoea and contraception can be ceased at this time for patient over 50.
- For patient aged between 40-50, it is recommended that contraception be continued for an additional year (2 years of amenorrhoea).

Working with Aboriginal and Torres Strait Islander people

- Sexual health is often not openly discussed in Aboriginal and Torres Strait Islander cultures and 'shame' (a deeply internalised feeling of inadequacy, self-doubt or ostracism) may be a strong barrier to First Nations people seeking sexual health care or contraception, especially in the community pharmacy setting in smaller communities.
- All health care providers must be cognisant of causing additional 'shame' to Aboriginal and Torres Strait Islander people while providing reproductive counselling or advice.
- It *may* be necessary (but not always) and beneficial to refer Aboriginal and Torres Strait Islander people seeking contraception to a medical practitioner or health service/clinic where the person has an existing relationship (if the person consents).

Sexual and domestic abuse

- Pharmacists must be aware of the possibility that a woman seeking contraception may be and/or have been subjected to sexual violence or abuse (assault or sexual coercion), either within a relationship or outside of a relationship.
- If the pharmacist becomes aware of this during the consultation, they should provide appropriate support and assistance, including referral to support options depending on the patient circumstances:
  - Referral options include to the local hospital, sexual health clinic and/or community-based sexual violence support services. A list of family violence statewide support services including confidential crisis support, information and counselling in Victoria is available at: https://www.vic.gov.au/family-violence-statewide-support-services.
- If required, emergency contraception may be supplied as per standard pharmacy care, or the person may be referred to an appropriate medical practitioner or health service for another method of emergency contraception e.g. insertion of a copper intrauterine device.

Contraceptive options and information for transgender and non-binary people

- Pharmacists should check that transgender (trans) and non-binary people requesting contraceptive care have been engaging with specialist sexual health services to ensure they receive comprehensive and culturally safe sexual health care that is tailored to their individual needs:
  - Sexual Health Victoria offers a range of sexual health services for the lesbian, gay, bisexual, transgender, intersex, queer, and asexual/aromantic community, with information available at https://shvic.org.au/for-you/lesbian-gay-bisexual-transgender-intersex-lgbti.

4.2. PATIENT HISTORY

Sufficient information must be obtained from the patient to assess the safety and appropriateness of any recommendations and medicines, including resupply of the OCP, for the patient. Review MHR where available and appropriate.

Consider:

- Age
- Pregnancy and breastfeeding status
- Underlying medical conditions, including new or recently diagnosed medical conditions, which may:
  - be a contraindication to hormonal contraception e.g. migraine with aura
  - impact on contraceptive effectiveness and choice
- Current medications, including check adherence and satisfaction with OCP
- Drug allergies/adverse effects, including any adverse effects of OCP
- Smoking status (there is an increased VTE risk in smokers over 35 years)
- BMI

- Last STI screen and Cervical Screening Test (CST)*
- Presence of genitourinary symptoms that may suggest STI:
  - Changes in vaginal or urethral discharge
  - Vulval, genital skin problems or symptoms
  - Lower abdominal pain
  - Dysuria
- HPV vaccination status.

* All patients seeking contraception who have not had a CST in the previous 5 years should be advised to see a medical practitioner for a CST, and a referral provided if the patient consents. They are still eligible for the OCP resupply service in the Pilot.

Sexual history

In addition to a standard patient history, pharmacists must also consider taking a brief sexual history from the patient to inform shared decision making/appropriateness of OCP resupply.

The following issues may be considered but may not be relevant to all people: previous use and experiences with contraception, current relationship status and risk factors for STIs (including STI history of current and/or recent partner if applicable).

Guidance and information on how to take a sexual history is available at: https://sti.guidelines.org.au/sexual-history/.

4.3. EXAMINATION

The pharmacist should measure BP and calculate BMI to determine the person's suitability for continuing their OCP.

A single elevated BP reading is not enough to classify a woman as hypertensive (e.g. also take into consideration activity immediately prior to consultation) and a second BP reading should be taken at the end of the consultation. If BP remains elevated, the patient should be referred to a medical practitioner for further assessment and selection of an appropriate contraceptive method.

Refer the person to GP when:

Pharmacists must refer patients to a medical practitioner (or sexual health clinic) if:

- younger than 16 or over 50 years of age
- not currently taking and wants to restart
- request is for a different OCP or a different type of contraception, e.g. a LARC
- requested OCP is not on the protocol medicines list
- requested OCP is now contraindicated or not appropriate, e.g. hypertensive, BMI> 35
- unexplained and un-investigated vaginal bleeding or acute, severe menstrual bleeding
- potentially pregnant
- STI screening is indicated (although OCP may still be resupplied by the pharmacist).

5. Confirm OCP resupply/ contraception plan is appropriate

Pharmacists must consult the Therapeutic Guidelines, Australian Medicines Handbook and other relevant references to confirm the OCP is appropriate for the patient, including for:

- Contraindications and precautions
- Drug interactions
- Pregnancy and lactation.

5.1. EXCLUDING PREGNANCY

If the patient is still taking the OCP and there are no symptoms or signs of pregnancy, they can be reasonably assumed not to be pregnant. **However if there is any doubt regarding whether the patient may be pregnant, the patient should be advised to take a pregnancy test and provided this is negative, they may then return to the pharmacy for the resupply of their OCP**.

6. Medicines list

The Pilot authorises the resupply of two types of oral hormonal contraceptive pills: the combined oral contraceptive pill (COCP) and the progestogen only pill (POP or mini pill), specifically those that are listed in the table below.

Note: COCPs with a high estrogen dose (50 micrograms of ethinylestradiol or equivalent) are not routinely recommended for contraception because of the unacceptable risk of VTE and have been excluded from the Pilot.

Combined oral contraceptive pills (COCP)

Estrogen dose (micrograms)	Progestogen dose (micrograms)	Brand name examples
Monophasic oral formulations: low-dose estrogen		
ethinylestradiol 20*	levonorgestrel 100	Femme-Tab ED 20/100, Lenest 20 ED, Loette, Microgynon 20 ED, Micronelle 20 ED
	drospirenone 3000	Yaz
estradiol 1500	nomegestrol 2500	Zoely
Monophasic oral formulations: standard-dose estrogen		
ethinylestradiol 30*	levonorgestrel 150	Eleanor 150/30 ED, Evelyn 150/30 ED, Femme-Tab ED 30/150, Lenest 30 ED, Levlen ED, Microgynon 30 ED, Micronelle 30 ED, Monofeme, Nordette, Seasonique
	desogestrel 150	Madeline, Marvelon
	dienogest 2000	Valette
	drospirenone 3000	Petibelle, Yasmin
	gestodene 75	Minulet
ethinylestradiol 35	cyproterone 2000	Diane-35 ED, Estelle-35 ED, Juliet-35 ED, Brenda-35 ED
	norethisterone 500	Brevinor, Norimin
	norethisterone 1000	Brevinor-1, Norimin-1, Pirmella
Triphasic: low or standard dose estrogen		
Phase 1 (6 pills): ethinylestradiol 30 + levonorgestrel 50 Phase 2 (5 pills): ethinylestradiol 40 + levonorgestrel 75 Phase 3 (10 pills): ethinylestradiol 30 + levonorgestrel 125		Logynon ED, Trifeme, Triphasil, Triquilar ED
Quadriphasic: low or standard dose estrogen		
Phase 1 (2 pills): estradiol valerate 3000 alone Phase 2 (5 pills): estradiol valerate 2000 + dienogest 2000 Phase 3 (17 pills): estradiol valerate 2000 + dienogest 3000 Phase 4 (2 pills): estradiol valerate 1000 alone		Qlaira

* NB: first-line choice of COCP is a monophasic formulation containing ethinylestradiol (20 or 30 micrograms) and levonorgestrel (Therapeutic Guidelines)

Progestogen only pills (POP) oral contraception

Progestogen dose (micrograms)	Brand name examples
Levonorgestrel 30 micrograms	Microlut
Norethisterone 350 micrograms	Noriday
Drospirenone 4 micrograms	Slinda

7. Communicate agreed plan for OCP resupply

Offering comprehensive counselling that covers adverse effects, instructions for use and patient expectations where this is required assists to promote effective and ongoing contraceptive use.

Comprehensive advice and counselling (including supporting written information when required) as per the Therapeutic Guidelines, Australian Medicines Handbook, UKMEC 2016, and other relevant references, should be provided to the patient regarding:

- Individual product and medicine use,
- Managing missed pills and emergency contraception options available if required
- How to manage adverse effects
- When to seek further care and/or treatment:
  - The signs of VTE and what to do if it is suspected
  - The importance of reporting new or worsening mood-related symptoms to the pharmacist and usual medical practitioner.

7.1. GENERAL ADVICE

Patient resources

Where appropriate, individuals may be provided with additional resources to support sexual health. It is the pharmacist's responsibility to ensure the suitability and accuracy of any resources provided, and to ensure compliance with all copyright conditions.

Factsheets and other information suitable for patients on the OCP and sexual health include:

- The Victorian Government's Better Health Channel information on 'Oral contraceptive pills', 'Safe sex' and 'Emergency contraception':
  - https://www.betterhealth.vic.gov.au/health/healthyliving/contraception-choices#oral-contraceptive-pills
  - https://www.betterhealth.vic.gov.au/health/healthyliving/safe-sex
  - https://www.betterhealth.vic.gov.au/health/healthyliving/contraception-emergency-contraception
- Sexual Health Victoria (formerly Family Planning Victoria):
  - Reproductive & Sexual Health Clinics, Education and Advocacy (shvic.org.au)
- 1800MyOptions helpline and website:
  - Provides information about contraception, pregnancy options and sexual health in Victoria. Phone: 1800 696 784, open 9am to 5pm Mon to Fri https://www.1800myoptions.org.au/.

8. Follow up

Pharmacists should advise the patient that they can seek a resupply of their OCP at the pharmacy when they next need a replacement pack (approximately four months later depending on OCP pack size) and that the OCP resupply service will be available for at least the duration of the Victorian Pilot (to October 2024).

It is recommended that:

- The patient's BP should be monitored at 12 monthly intervals, and
- Patients should be reviewed by their GP at least every 2 years.

9. Resources for pharmacists

Therapeutic Guidelines: Sexual and Reproductive Health [digital]

Australian Medicines Handbook: Drugs for contraception

The Faculty of Sexual & Reproductive Healthcare of the Royal College of Obstetricians and Gynaecologists. The UK Medical Eligibility Criteria for Contraceptive Use (UKMEC): FSRH; 2019 [cited 24 August 2023]. Available from: https://www.fsrh.org/standards-and-guidance/uk-medical-eligibility-criteria-for-contraceptive-use-ukmec/

The Faculty of Sexual & Reproductive Healthcare of the Royal College of Obstetricians and Gynaecologists. Combined Hormonal Contraception (January 2019, amended July 2023): FSRH [cited 24 August 2023]. Available from: https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/

The Faculty of Sexual & Reproductive Healthcare of the Royal College of Obstetricians and Gynaecologists. Progestogen-only Pills (August 2022, amended July 2023): FSRH [cited 24 August 2023]. Available from: https://www.fsrh.org/standards-and-guidance/documents/cec-guideline-pop/

Pharmaceutical Society of Australia Women's Sexual and Reproductive Health: Women's sexual and reproductive health (psa.org.au)

Leanne Philpott. Empowering choice through contraception advice (19 August 2023). Australian Journal of Pharmacy. Accessed at: https://ajp.com.au/news/empowering-choice-through-contraception-advice/

Professional Practice Standards 2023

https://www.psa.org.au/practice-support-industry/pps/

Patient information

Better Health Channel 'Oral contraceptive pills': https://www.betterhealth.vic.gov.au/health/healthyliving/contraception-choices#oral-contraceptive-pills

Better Health Channel 'Safe sex': Safe sex - Better Health Channel

Sexual Health Victoria: Reproductive & Sexual Health Clinics, Education and Advocacy (shvic.org.au)

Melbourne Sexual Health Centre: expert sexual health information, advice, testing, treatment and support https://www.mshc.org.au/

1800MyOptions: information about contraception, pregnancy options and sexual health in Victoria https://www.1800myoptions.org.au/ ph:1800 696 784, Open 9am to 5pm Mon to Fri

Jean Hailes contraception fact sheet: https://www.jeanhailes.org.au/resources/fact-sheets/contraception


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