

Medicines, Poisons and Therapeutic goods (Pharmacist Extended Scope of Practice – Hormonal Contraception) Authorisation 2025 (No 1)

Notifiable instrument NI2025–611

made under the

Medicines, Poisons and Therapeutic Goods Regulation 2008, Section 490A (Approvals of dealings by health practitioners – Act, s 20 (1) (c))

1 Name of instrument

This instrument is the Medicines, Poisons and Therapeutic Goods (Pharmacist Extended Scope of Practice- Hormonal Contraception) Authorisation 2025 (No 1).

2 Commencement

This instrument commences the day after notification.

3 Authorisation

A pharmacist is authorised to supply medicine or a class of medicines to a person without a prescription if the supply is performed in accordance with the ACT Pharmacist Extended Scope of Practice - Hormonal Contraception Authorisation as set out in Schedule 1 of this document.

Dr Kerry Coleman
Chief Health Officer
30 October 2025

ACT Pharmacist Extended Scope of Practice

Hormonal Contraception Authorisation

Introduction

This Pharmacist Extended Scope of Practice Authorisation (Hormonal Contraception Authorisation) is made under schedule 490A of the Medicines, Poisons and Therapeutic Goods Regulation 2008 for the purposes of establishing conditions and criteria under which a registered pharmacist may continue the supply of the particular medicine or class of medicine to which the authorisation relates in the absence of a supply authority (prescription).

This Hormonal Contraception Authorisation should be read in conjunction with the *Medicines, Poisons and Therapeutic Goods Act 2008*, the Medicines, Poisons and Therapeutic Goods Regulation 2008 (from www.legislation.act.gov.au) to ensure pharmacists are fully aware of their obligations when providing services.

Authorisation for pharmacists to supply medicines

A registered pharmacist[#] may deal with a medicine or a class of medicine to which the authorisation relates to under their own authority (without a prescription) to a person under the following conditions:

- The medicine is listed under Part A – Medicines Authorisations;
- The patient is eligible under the “patient eligibility criteria” under the relevant section of Part A – Medicines Authorisations;
- Any other conditions listed under the relevant section of Part A – Medicines Authorisations;
- The prescribed training requirements listed under the appropriate section of Part B – Pharmacist Training Requirements are met;
- The patient and the pharmacist must both be physically present at a pharmacy that meets the listed requirements of Part C – Premises Standard, for consultation with the patient to occur prior to supply.
- The prescribed record keeping requirements listed under Part D – Record Keeping Requirements are met;
- Pharmacists must follow all clinical protocols, if any clinical protocols are approved, under the appropriate section of Part E – Clinical Protocols;
- Pharmacists must comply with Australian Health Practitioner Regulation Agency (AHPRA) and the Pharmacy Board of Australia Code of Conduct, and the expected standards of ethical behaviour of pharmacists towards individuals, the community and society. Breaches will be dealt with in accordance with Part F- Governance and Complaints; and
- The pharmacist must consider any supplemental information and notes listed at Appendix 2 – Supplementary Information and Notes.

[#] A Pharmacist is a person who holds registration under the Health Practitioner Regulation National Law (ACT) and is employed or engaged in a pharmacy that meets the requirements in Part C.

***For further information about this authorisation please contact the Health
Protection Service on 5124 9700 or at HPS@act.gov.au***

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Part A - Medicines Authorisations

i. Approved Medicines

Eligible pharmacists may supply the following medicines, in their single or combined oral forms for oral contraception (OC):

- Ethinylloestradiol (40µg or less)
- Levonorgestrel
- Norethisterone
- Drospirenone (single ingredient preparations only)

ii. Eligible Patients

Eligible pharmacists can supply OC to women and people with a uterus aged 18 years to 49 years who have been supplied or prescribed the oral contraceptive pill by a medical practitioner or nurse practitioner for the previous 24 months, with continuous use.

The flowchart provided in Appendix 1 should be used to assess the eligibility, identity, govern the supply of suitable treatments, and guide associated referral requirements. This flowchart should be read alongside with all the information provided in Section G.

iii. Other Conditions

Supply of OC services is subject to the following conditions:

- The supply to the patient must be primarily for the purpose of oral contraception,
- The patient must have been treated with the eligible medicine for the past 24 months and that use has been continuous,
- The pharmacist must ensure the patient will not be supplied any OC medicine by a pharmacist acting under this authority for a period exceeding 12 months,
- The patient and the pharmacist must both be physically present at a pharmacy that meets the listed requirements of Part C – Premises Standard.

iv. Adverse Effects

If the treating pharmacist becomes aware of an uncommon, unexpected or serious adverse event following treatment with an Approved Medicine, this should be reported to the Therapeutic Goods Administration. This should be conducted via the usual processes, by reporting online at <https://aems.tga.gov.au/>

Part B - Pharmacist Training Requirements

Pharmacists are considered to have appropriate training and competence to administer extended scope of practice services in the ACT, as outlined in this instrument, if they hold current registration with the Pharmacy Board of Australia under the Australian Health Practitioner Regulation Agency (AHPRA), and have completed an Accredited clinical training course as described below:

- Pharmaceutical Society of Australia – Contraception Essentials, **OR**
- Australasian College of Pharmacy Oral - Contraceptives: a comprehensive training course for pharmacists, **OR**
- James Cook University – Extended Community practice pharmacists’ course – Professional Practice for Pharmacists 1 (Subject PC6100) and Professional Practice for Pharmacists 2 (Subject PC6200), **AND**
 - The Queensland University of Technology’s Safe prescribing and quality use of medicines course, **OR**
 - James Cook University’s Safe Prescribing for Pharmacists (subject PC6300),
- Any other Accredited training recognised or required by the Chief Health Officer

Part C - Premise Standards

For a pharmacist to supply extended scope of practice services, the services must be provided in a pharmacy that meets the following requirements:

- Maintain up-to-date service availability listings on Health Direct;
- Has a consulting room consistent with the following:
 - is not to be used for any other purpose (such as a dispensary, storeroom, staff room or retail area),
 - is fully enclosed and provides adequate privacy for confidential conversations and any required examination (a divider or curtain in a dispensary, storeroom, staff room or retail area is not acceptable),
 - has adequate lighting,
 - is maintained at a comfortable ambient temperature,
 - has hand sanitisation facilities, and
 - has sufficient floor area, clear of equipment and furniture, to accommodate the applicable patient receiving the consultation and an accompanying person, and to allow the pharmacist adequate space to manoeuvre.

Part D - Record Keeping Requirements

After providing a service under this authorisation, pharmacists are required to complete a full clinical record and should share a record of the consultation with the patient's usual treating medical practitioner, with the client's consent.

Full Clinical Record

Pharmacists are required to make a full clinical record of the consultation using secure digital software. Records must be stored securely for a minimum of seven years and must contain:

- Sufficient information to identify the patient;
- The date of the consultation;
- The name of the pharmacist who undertook the consultation and their Healthcare Provider Identifier – Individual;
- Any information known to the pharmacist that is relevant to the patient's diagnosis or treatment (for example, information concerning the patient's medical history, including new or recently diagnosed conditions with a UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) 3 and 4);¹
- Any clinical opinion reached by the pharmacist;
- Actions and management plan taken by the pharmacist;
- Particulars of any medication supplied for the patient (such as form, strength and amount);
- Notes or advice given to the patient in relation to any treatment proposed by the pharmacist who is treating the patient;
- Any consent given by a patient to the consultation, supply of medication and treatment proposed; and
- Any referrals made to a medical practitioner or other healthcare professional.

Sharing Clinical Record

The pharmacist must seek the patient's consent to share a record of the consultation and any subsequent consultations (including adverse events) with the patient's usual treating medical practitioner or medical practice, where the patient has one, following consent by the patient. If the patient **does** consent to the disclosure, the record must be shared within seven (7) days following the consultation.

Communication with the patient's usual treating medical practitioner or medical practice should ensure patient confidentiality is maintained. Use of a secure digital messaging platform is considered best practice.

Part E - Clinical Protocols

All pharmacists must act in accordance with the approved OCP Clinical Protocol as included in **Appendix 1**.

¹ The College of Sexual & Reproductive Healthcare, "UK Medical Eligibility Criteria for Contraceptive Use (UKMEC)" (2016) <<https://www.cosrh.org/Public/Public/Standards-and-Guidance/uk-medical-eligibility-criteria-for-contraceptive-use-ukmec.aspx>>

Part F - Governance and complaints

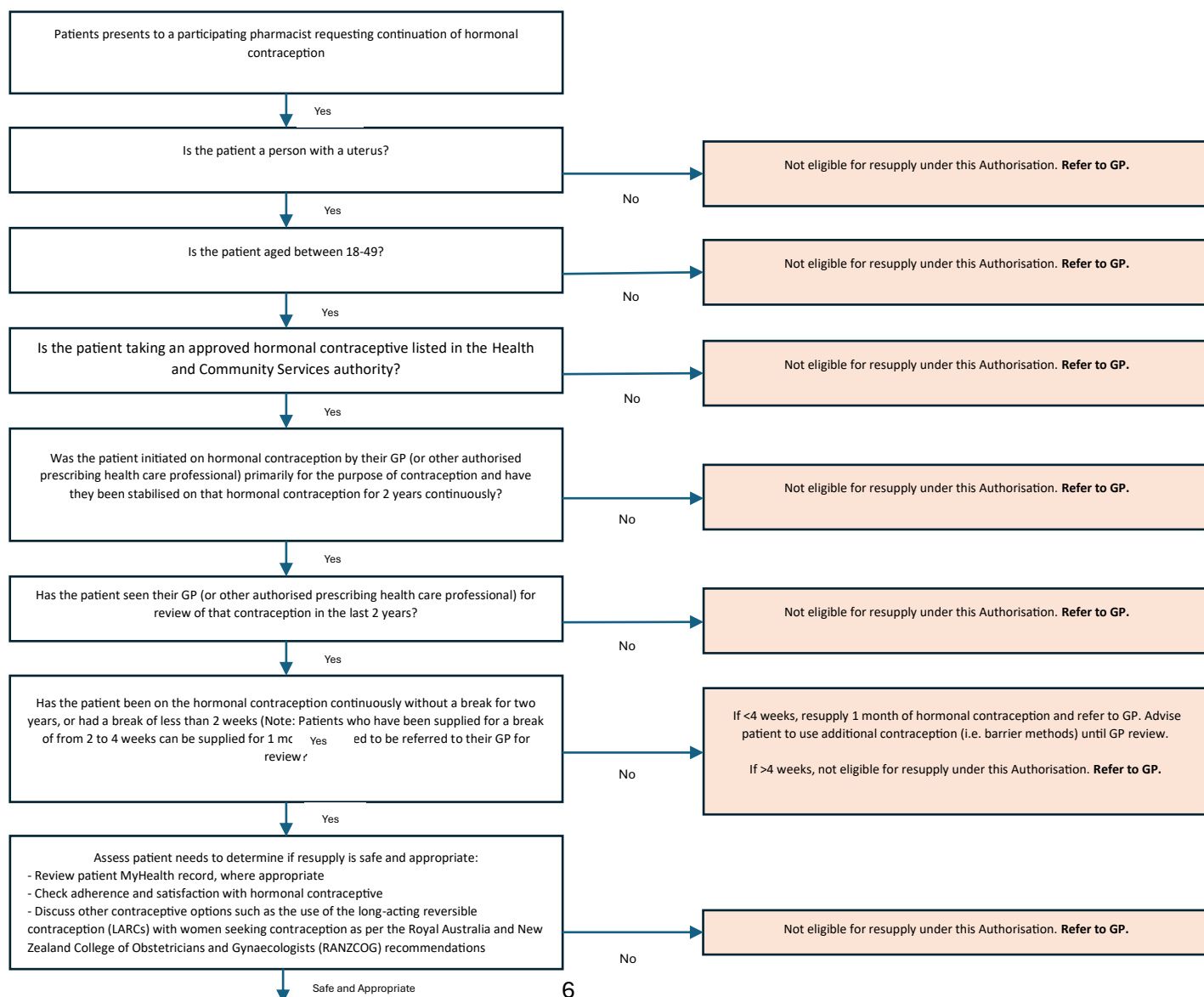
The Health and Community Services Directorate (HCSD) takes an educate and engage approach to regulation including for activities under the *Medicines, Poisons and Therapeutic Goods Act 2008*. This approach focuses on providing education directly to community pharmacists choosing to offer extended scope of practice services to ensure they understand their roles and responsibilities. Pharmacists are expected to follow the AHPRA Code of Conduct.

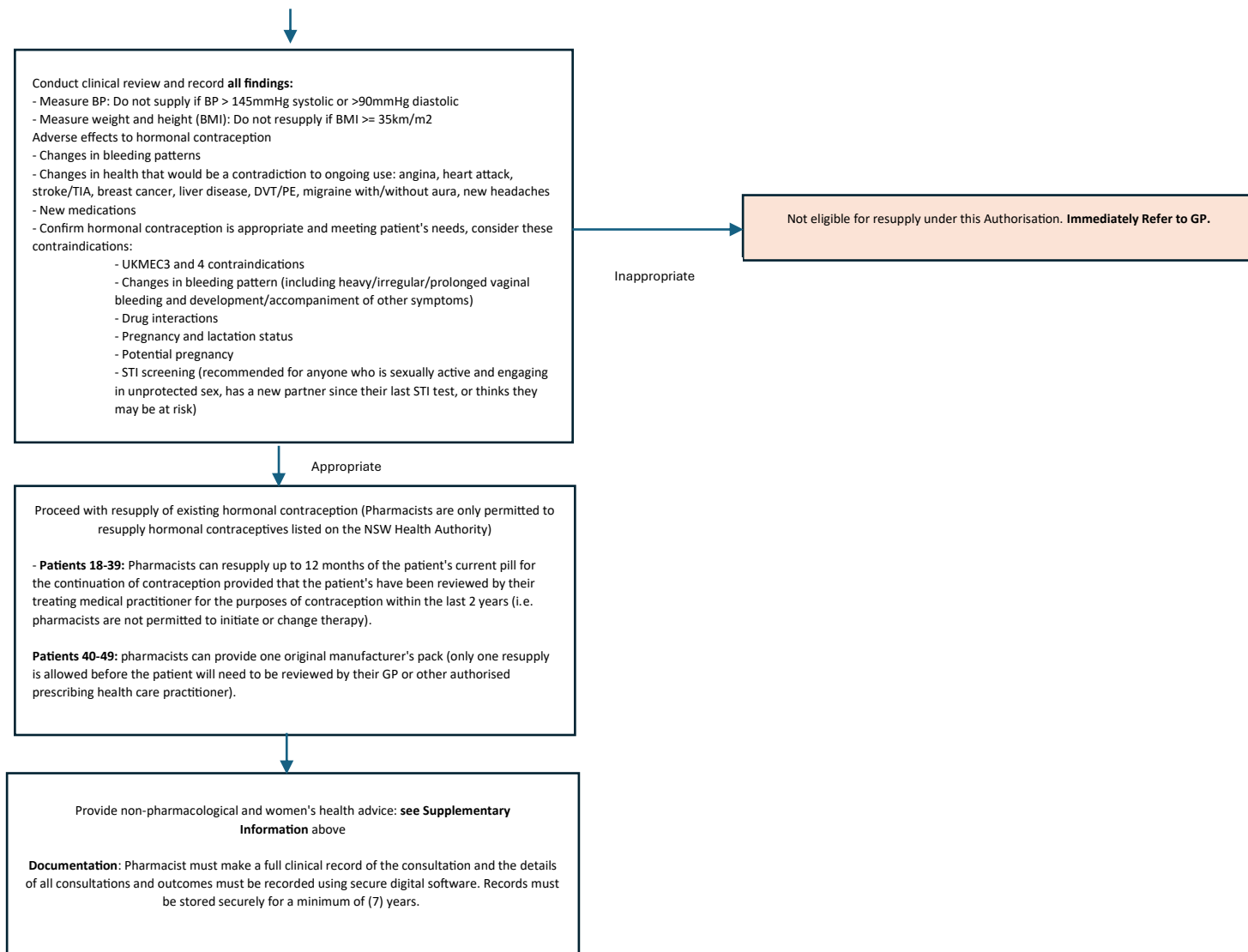
Contravening any condition of this authorisation is grounds for disciplinary action under Section 140 of the *Medicines, Poisons and Therapeutic Goods Act 2008 - Grounds for disciplinary action against authorisation holders*. A contravention of Section 140 of the Act may result in disciplinary action under *Section 141 - Disciplinary action against authorisation holders*.

Reports of unsafe practices, poor clinical practice or failure to adhere to the Code of Conduct may be reported to AHPRA and/or the ACT Health Services Commissioner.

Appendix 1 – OCP Clinical Protocol

This clinical protocol has been adapted from the NSW Pharmacist Practice Standards for the Continuation of Hormonal Contraception created by NSW Health and is used with permission.





Appendix 2 – Supplemental Information and Notes

This supplementary information provides additional guidance and information for pharmacists. It is to be used together with the flowchart and training modules and other resources provided by education providers.

Key points

- The ACT Pharmacist Extended Scope of Practice Hormonal Contraception Authorisation provides a framework for pharmacists to resupply oral contraception to eligible patients in the ACT.
- To receive a resupply of hormonal contraception, the patient must fulfill the eligibility requirements of the Practice Standard. Patients who have requested the service but are not eligible for resupply should be referred to their regular medical practitioner or health service.
- Pharmacists can resupply up to 12-months² of the patient's current hormonal contraception if it has been prescribed primarily for the purpose of contraception provided the patient has been reviewed by their treating medical practitioner or health service for the purposes of contraception within the last 2 years (i.e. pharmacists are not permitted to initiate or change therapy).
- Pharmacists must only resupply formulations listed in the Authority.
- Patients must be physically present in the pharmacy to be eligible for resupply.
- Patients are required to have a private pharmacist consultation, including blood pressure monitoring, before a hormonal contraceptive method may be resupplied.
- Pharmacists must make a full clinical record of the consultation and the details of all consultations and outcomes must be recorded using secure digital software. Records must be stored securely for minimum seven (7) years.
- Pharmacists may prefer to supply the contraceptive pill utilising the Pharmaceutical Benefits Scheme Continued Dispensing Arrangements for eligible patients. Continued Dispensing under the PBS may reduce the cost of these medicines to the patient, particularly for those with a health care card.

Clinical Documentation and Communication

- The pharmacist must make an electronic clinical consultation record, as well as a record of dispensing in the pharmacy's dispensing system, in accordance with the Authority.
- Where a patient has a My Health Record, the pharmacist should ensure the details of the hormonal contraception supply are uploaded to the patient's My Health Record, unless requested otherwise by the patient.

²For patients aged 40-49: pharmacists can only provide one original manufacturer's pack (only one resupply is allowed before the patient will need to be reviewed by their GP or other authorising prescribing healthcare practitioner).

Patient History

- Sufficient information must be obtained from the patient to assess the safety and appropriateness of resupply of the hormonal contraception. The patient's My Health Record should be reviewed where appropriate and available.
- The patient history should include:
 - Age
 - Pregnancy and breastfeeding status
 - Underlying medical conditions, including new or recently diagnosed medical conditions (see UK Medical Eligibility Criteria [UKMEC] 3 and 4^[1]), which may:
 - Be a contraindication to hormonal contraception e.g. migraine with aura (patients with a UKMEC category 3 or 4 condition are not eligible for resupply and require a referral)
 - Impact on contraceptive effectiveness and choice
 - Current medications, including adherence and satisfaction with hormonal contraception
 - Pharmacists must ascertain whether use of hormonal contraception has been continuous and can resupply according to the Practice Standard.
 - If a patient frequently takes pill breaks, pharmacists should use professional judgement and consider referring the patient to explore alternative contraception options e.g. long-acting reversible contraception (LARCs).
 - Drug allergies/adverse effects, including any adverse effects of hormonal contraception
 - Prior use of contraceptives, tolerability, and adverse effects
 - Smoking status, including vaping:
 - There is an increased risk of using hormonal contraception in smokers over 35 years.³
 - Any unexplained and un-investigated vaginal bleeding or acute, severe menstrual bleeding
 - Any headaches indicative of migraines o Last Cervical Screening Test⁴ and Breast check
 - HPV vaccination status

Sexual and social history

- In addition to a standard patient history, pharmacists should consider taking a brief sexual history from the patient to inform shared decision making/appropriateness of hormonal contraception 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

³ [Family Planning Alliance Australia](#) recommends: 'Until further evidence is available, vaping with nicotine is considered equivalent to cigarette smoking in relation to the MEC for contraceptive use. As it is not possible to determine equivalency of exposure between vaping and smoking, any vaping in those aged 35 years and older will be MEC 4 (i.e. absolutely contraindicated) for use of combined hormonal contraception.'^[13]

⁴All patients seeking contraception who have not had a cervical screening test (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 hormonal contraception resupply service.

information on how to take a sexual history is available at:

<https://sti.guidelines.org.au/sexual-history/>.^[2]

Sexually transmitted infection (STI) screening

- STI screening is recommended for anyone who is sexually active and engaging in unprotected sex, has a new partner since their last STI test, or thinks they may be at risk.
- Pharmacists should recommend STI testing for individuals who may be at risk even if the individual does not report any symptoms.
- Presence of genitourinary symptoms that might suggest a STI: changes in vaginal or urethral discharge; vulval, genital skin problems or symptoms; lower abdominal pain; dysuria.
- Aboriginal and Torres Strait Islander People are disproportionately affected by STIs. Consider the [Australian Consensus STI Testing Guideline for Aboriginal and Torres Strait Islander People](#) for priority populations testing and frequency or recommendations on STI screening.^[3]

Bleeding pattern and menstrual history

- Any changes in vaginal bleeding and the development or accompaniment of other symptoms may indicate underlying pathology. This requires referral to a medical practitioner or health service for further investigation and management.
- Changes in bleeding pattern may include abnormalities in frequency (e.g. heavy bleeding), irregular bleeding, prolonged menstrual bleeding, abnormalities in volume, intermenstrual bleeding, and post-coital bleeding.
- Development or accompaniment of other symptoms may include dysmenorrhea (pain and cramping with bleeding), vaginal discharge, dyspareunia (pain with intercourse), changes in bladder or bowel function, weight gain or loss, headaches, visual disturbances, hirsutism, and acne.

Women over 40

- Despite a natural decline in fertility, women over 40 require ongoing contraception until they reach menopause if they wish to avoid unplanned pregnancy.
- As per the Faculty of Sexual and Reproductive (FSRH), women over 40 have an age-related increased background risk of cardiovascular disease, obesity, breast cancer and most gynaecological cancers.^[4] As a result, choice of contraceptive method needs to be reviewed with their medical practitioner or health service.
- Women over 35 who smoke should be advised to stop combined hormonal contraception as the risk of mortality associated with smoking becomes clinically significant at this point.
- Women over 50, should be advised to no longer use combined hormonal contraception as there are safer methods of contraception at this point.^[5]

EXAMINATION

- The pharmacist should measure blood pressure (BP) and the patient's height and weight to calculate BMI to determine the patient's suitability for continuing their OCP and record this information in their clinical software program.
- Note that a single elevated BP reading is not enough to classify an individual as hypertensive (note that activity immediately prior to consultation should also be taken into consideration) 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 or health service for further assessment and selection of an appropriate contraceptive method.

- BP should be monitored and recorded every 12 months.
- BMI should be calculated on the first presentation, and professional judgement exercised regarding whether BMI needs to be recalculated on subsequent presentations (i.e., consider length of time between presentations, changes in body weight).

SEXUAL AND REPRODUCTIVE HEALTH COUNSELLING

Sexual and domestic abuse

- Pharmacists must be aware of the possibility that a woman seeking contraception may be and/or has 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. Lists of family violence support services in both the ACT and NSW, including confidential crisis support, information and counselling are available at the [ACT Government Domestic, Family and Sexual Violence](#) and the [NSW Government Domestic, Family and Sexual Violence](#).^{[6][7]}
 - 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.

Transgender, gender diverse and non-binary people

- These services are inclusive of transgender, gender diverse, intersex or nonbinary people assigned and/or presumed female at birth - current gender identity does not impose any restrictions on methods of contraception that may be used; the same considerations apply for choosing safe and effective contraception, including personal characteristics, existing medical conditions and current medicines.
- Pharmacists may refer individuals assigned and/or presumed female at birth who are at risk of pregnancy to a general practitioner or specialist sexual health services, if not already engaging with these services, to ensure that they receive comprehensive and culturally safe sexual healthcare that is tailored to their individual needs.

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 where the person has an existing relationship (if the person consents).

Provision of non-pharmacological and women's health advice

- 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, and other relevant resources, should be provided to the patient:
 - Consumer Medicines Information and/or other resources/handouts endorsed by relevant organisations.
 - Appropriate counselling on the hormonal contraception supplied, (i.e., how to take, side effects to expect/how to manage side effects, when the OC is less effective, what to do in the event of a missed pill, reiterate the importance of adherence and avoiding starting/stopping the pill)
 - Educate patients on the importance of getting regular women's health and sexual/reproductive health checks
- If patients have a concern with the type of hormonal contraception they are using, encourage them to speak with their medical practitioner or health service and make appropriate referrals.
- Presentations to the community pharmacy for contraceptive resupply provide an important opportunity to engage patients in preventative healthcare, such as screening, education, vaccination, and referral to a medical practitioner or health service where appropriate. Patients should be provided information about and be encouraged to make an appointment for the following screening:
 - Cervical screening – routine screening is available for people from the age of 25 and is recommended every five years
 - Breast checks – people who have a personal or family history of breast cancer, should be advised to see their medical practitioner or health service for advice regarding frequency and type of screening
 - STI screening – recommended for anyone who is sexually active and engaging in unprotected sex, has a new partner since their last STI test, or thinks they may be at risk.
 - Pharmacists may also discuss the use of LARCs with patients when appropriate, as per the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) recommendations. See [Long-Acting Reversible Contraception \(LARC\) - Consensus Statement](#) for further information.^[8]

CONTRAINDICATIONS TO HORMONAL CONTRACEPTION

1. The [Therapeutic Guidelines - Contraception](#) indicates a range of contraindications and precautions for combined hormonal contraception and progestogen-only oral contraception.^[9] These are based on the UK Medical Eligibility Criteria (UKMEC) and include conditions in Table 1 and 2 (not an exhaustive list).
2. For a full list of UKMEC 3 and UKMEC 4 classified conditions, see:
 - [FSRH Guideline Combined Hormonal Contraception](#)^[10]
 - [FSRH Clinical Guideline: Progestogen-only Pills](#)^[11]
 - [FSRH UK Medical Eligibility Criteria for Contraceptive Use](#)^[1]

- [FSRH Progestogen-only Injectable Contraception](#) ^[12]
- [RANZCOG Contraception Clinical Guideline](#) ^[4]

Table 1: Contraindications to Resupply of Combined Hormonal Contraceptives

UKMEC Category 3 and 4 contraindications and other conditions that require immediate referral
<ul style="list-style-type: none"> ▪ Current or previous history of breast cancer (including carriers of known gene mutations associated with breast cancer) ▪ Migraine with/without aura ▪ Current or past history of ischaemic heart disease, stroke or transient ischaemic attack ▪ Aged 35 years or older and current smoker or recently quit smoking (including nicotine vaping*) in the last 12 months ▪ Hypertension (systolic blood pressure 140 mmHg or higher, or diastolic blood pressure 90 mmHg or higher), including adequately controlled hypertension ▪ Hypertension, with vascular disease ▪ Complicated valvular or congenital heart disease ▪ Cardiomyopathy with impaired cardiac function ▪ Atrial fibrillation ▪ Current or past history of VTE or a first-degree relative with a VTE (provoked or unprovoked) under the age of 45 years ▪ Positive antiphospholipid antibodies ▪ Known thrombogenic mutations, e.g. factor V Leiden, prothrombin mutation, Protein S, Protein C, antithrombin deficiencies ▪ Prolonged immobilisation ▪ Severe (decompensated) cirrhosis ▪ Hepatocellular adenoma or malignant liver tumour ▪ Body mass index (BMI) 35 kg/m² or more ▪ Diabetes with nephropathy, retinopathy, neuropathy or other vascular disease ▪ Gall bladder disease (medically treated or current) ▪ Undiagnosed mass/breast symptoms (only if the condition is pre-existing and the COCP is initiated) ▪ Multiple risk factors for cardiovascular disease (such as smoking, diabetes, hypertension, obesity, and dyslipidaemias) ▪ Past COC related cholestasis ▪ Organ transplant ▪ Complicated: graft failure (acute or chronic), rejection, cardiac allograft vasculopathy ▪ Acute viral hepatitis, or flare (only if the condition is pre-existing and the COC is initiated)

Table 2: Contraindications to Resupply of Progesterone Only Pill

UKMEC Category 3 and 4 contraindications and other conditions that require immediate referral
<ul style="list-style-type: none"> ▪ Current or previous history of breast cancer ▪ Unexplained vaginal bleeding (suspicious for a serious condition) before investigation for the cause ▪ Severe (decompensated) cirrhosis ▪ Hepatocellular adenoma or malignant liver tumour • Ischaemic heart disease, stroke or transient ischaemic attack (TIA) that develops during use

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- [10] FRSH, “Guideline: Combined Hormonal Contraception,” January 2019, amended October 2023. [Online]
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- [11] FRSH, “Guideline: Progestogen-only Pills,” August 2022, amended July 2023. [Online]
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[12] FRSH, “Guideline: Progestogen-only Injectables”, December 2014, amended July 2023.

[Online]

Available: <https://www.fsrh.org/Common/Uploaded%20files/documents/progestogen-only-injectable-december-2014-amended-11july2023.pdf>

[13] Family Planning Alliance Australia, “Vaping and medical eligibility for hormonal contraception,” January 2020. [Online]

Available: https://shvic.org.au/assets/img/content/Vaping-and-medical-eligibility-for-hormonal-contraception_Dec20.pdf