RACGP
Royal Australian College *of* General Practitioners

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27 May 2021

Associate Professor Suzanne Nielsen
Chair, Advisory Committee on Medicines Scheduling
Department of Health
Therapeutic Goods Administration

Submitted via the TGA Consultation Hub

Dear Associate Professor Nielsen

Public consultation on proposed amendments to the Poisons Standard (oral contraceptives) – ACMS #34, June 2021

Thank you for inviting The Royal Australian College of General Practitioners (RACGP) to comment on proposed amendments to the Poisons Standard (oral contraceptives).

The RACGP is Australia's largest general practice organisation, representing over 43,000 members working in or toward a career in general practice. Each year, general practitioners (GPs) provide more than 160 million general practice services to more than 22 million Australians, with almost nine in 10 people consulting a GP.[1]

The RACGP does not support Application A or B due to patient health and safety concerns. The proposals are both unsafe and unnecessary. Women's health is more than just a prescription service. The increased risk to patients does not outweigh the doubtful benefits, for which there is no substantiation. The suggestion that advice provided by a health professional that has no access to patient history or interface with the patient's primary care provider would strengthen primary health care is both naïve and dangerous. Similarly, the argument of accessibility does not hold up in the current landscape of telehealth, e-prescribing and after-hours services.

Safe clinical governance frameworks must not be compromised unnecessarily for benefits of a dubious nature. Evidence and discussion supporting the RACGP's position are outlined in Appendix 1, along with proposed alternative ways to safely increase patient access to appropriate contraceptive services.

Thank you for taking the time to consider our submission. Should you wish to seek further comment from the RACGP, please contact myself or Ms Leonie Scott, National Manager – Policy and Advocacy, at leonie.scott@racgp.org.au or (03) 8699 0031 to arrange a meeting at your earliest convenience.

Yours sincerely

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Appendix 1

The RACGP's position is that safe clinical governance frameworks must not be compromised unnecessarily for the sake of benefits that are unsubstantiated.

1. Risks to patient safety and quality of care

Separation of dispensing and prescribing of medicines is critical to maintaining patient safety.

- Risk around contraceptive needs evolve over time. When a patient visits their GP for a repeat prescription, the GP takes the opportunity to review the patient's condition and the appropriate treatment. In the case of a patient 'just' obtaining a repeat prescription for the OCP, the GP will check the patient's blood pressure, offer important preventive interventions such as cervical screening, make sure there have been no relevant changes to lifestyle factors such as smoking status or sexual activity, and enquire about possible side effects such as migraines with an aura (which could indicate the patient is at risk of stroke), leg pains (which could indicate thrombosis), or changes to mental health.

  A patient obtaining additional supply of their medication directly from a pharmacy will bypass this necessary medical review. This poses unnecessary risk and could have negative consequences for their health and wellbeing.

- At a time when the community has an enhanced awareness of the risk of thrombosis, and the Prime Minister has publicly stated[2] that women are at greater risk of this life-threatening condition from taking the OCP (particularly proposal A's cyproterone) than after receiving the COVID-19 AstraZeneca vaccine, reducing clinical oversight of OCP prescribing is not prudent.

- Multiple studies agree that the provision of longer acting reversible contraceptive methods (LARCs) is likely to reduce unwanted pregnancy rates.[3] [4] Around 11% of Australian women use a LARC, a lower rate than many comparable countries.[5] [6] Any policy change that may reduce the likelihood of women choosing the contraceptive method that would be most clinically appropriate and effective is not desirable.

  It is important that women are encouraged to access contraceptive counselling and medical advice on LARCs. Removing the need to visit their GP for repeat prescriptions of the OCP will impact patient access to this important service.

- Medico-legal implications should also be considered. The responsibility for monitoring side effects, interactions, providing follow-up and access to after-hours care typically rests with the prescriber. The pharmacy business model does not allow for this level of care. Additionally, over the course of 12 months the patient may commence smoking, experience side effects such as migraines or leg pains, or experience other changes that require urgent reassessment of their suitability for the OCP. The RACGP questions where the legal responsibility will lie for any patient harm arising from reduced clinical oversight.

The RACGP receives numerous examples each year from our members where adverse outcomes appear to have occurred due to pharmacist advice. One such example is a patient who sought emergency supply of the OCP was dispensed a discontinued prescription for the mini pill they had once purchased at that pharmacy. Their GP had since prescribed a different type of OCP, which they had been purchasing from a different pharmacy. The mistake resulted in an unwanted pregnancy.

In another example, a teenage patient who had been taking the OCP for acne, subsequently became sexually active. This patient required additional counselling to understand the risk of sexually transmitted infections (STIs) even while taking the OCP. A patient's GP is best placed to raise these issues and have these discussions as part of a private consultation instead of the public spectacle of a retail shop.

2. There are safer ways that contraceptive access and compliance could be improved

There are several alternative pathways the RACGP would support, which would increase patient convenience and access to the OCP while maintaining safe clinical governance frameworks. These examples are provided to contrast against the proposals being considered by the TGA.

- If the goal is to increase patient convenience through time and cost savings, in many instances this could be achieved through 6- or 12-month dispensing (extended dispensing), removing the need for patients to regularly present to the pharmacy. Studies have shown that extended dispensing can improve drug compliance by reducing coverage gaps and reduce the number of resultant unintended pregnancies.[7] [8] [9]
- Contraceptive use and efficacy could be improved by focussing on policies which encourage the uptake of LARCs – including patient access to adequate contraceptive counselling, funding and support to improve medical practitioner understanding of the benefits of LARCs, and funding and processes which encourage more medical practitioners to offer insertion services.
- General practices are highly accessible to the community (see point 1 and 2). If it is thought that separation of prescribing and dispensing is not needed for the OCP, then GPs safely prescribe and can dispense medicines with appropriate clinical oversight.

  The RACGP supports including a greater range of oral medications in the PBS Prescriber's Bag, which allows general practices to appropriately supply medicines to manage urgent care.

  The PBS Prescriber's Bag is available to GPs practicing after-hours when local pharmacies may not be open, thus reducing delays for patients seeking access to necessary medicines.

  Alternatively, general practices are also perfectly placed to begin dispensing medicines under non-emergency situations to increase patient convenience and access to medicines.

3. Monitoring, evaluation, compliance and enforcement of Appendix M

The RACGP has previously raised concerns surrounding down-scheduled medicines.

- Evaluation of medicines down-scheduled from Schedule 4 to Schedule 3 must be made available to the public.
- There needs to be a process to monitor the unintended impacts of changes to scheduling that considers societal costs of overuse of medications and a shift from lifestyle interventions to pharmaceutical interventions.
- Given the heavy retail pressures experienced in community pharmacy, an evaluation program needs to document goals and health outcomes achieved, as well as costs to consumers.
- Pharmacies that participate in dispensing Appendix M drugs should be required to declare all commercial (financial and non-financial) arrangements with drug companies which supply the drugs in question.
- While monitoring compliance with Appendix M may be the responsibility of states and territories, the RACGP believes there needs to be national oversight including a system to audit any medicines dispensed from Appendix M.

4. There is no evidence of the need to increase access to the oral contraceptive pill (OCP)

It is unclear from the consultation document what problem the proposals aim to solve. Data does not show that patients are having difficulty accessing a GP for appointments:

- Nine in 10 Australians see a GP at least once each year.1
- Almost three in four Australians who need urgent medical care report they can see their GP within 24 hours. [10]
- Less than 1% of Australians who need to see a GP report they are unable to do so.[10]

No evidence regarding issues affecting women's ability to access the OCP in Australia have been presented to support either of the proposals.

5. Recent advances negate any argument that access to general practice is a barrier

The events of 2020 and subsequent policy and technology improvements have reduced the need for down-scheduling of the OCP.

The introduction of Medicare Benefits Schedule (MBS)-subsidised telehealth has improved the accessibility of general practice by ensuring patients can consult with their usual GP and receive a prescription from any location, including while in lockdown.

Electronic prescriptions further improve the timeliness of patient access to medicines and can be provided to the patient as part of a phone or video consultation with their GP.

As a last resort, emergency measures such as continued dispensing, prescription owing or emergency supply from pharmacies are available for the OCP, and can be expanded at short notice to include more medicines during emergency situations.

6. Feedback specific to the proposals

The RACGP does not support either proposal progressing. However, the below feedback is provided on the proposed Appendix M entries.

- *A previous prescription from a health professional is confirmed*

  This wording should be changed to "A previous prescription from a *medical* professional is confirmed".

  Recency of the previous prescription should also be confirmed, to try to determine if the patient's prescriber has since altered the prescription for clinical reasons.

- *The pharmacist is satisfied that the person's therapy is stable*

  The RACGP questions how a pharmacist will make this clinical decision based only on the duration of time the patient has been taking the OCP.

- *The person undergoes clinical review by a prescriber or pharmacist at least annually*

  The patient's condition must be reviewed by the prescriber. Allowing for this review to be undertaken by a pharmacist implies that dispensing from Schedule M could continue indefinitely without medical oversight.

- *The supply is appropriately recorded*

  Appropriate recording must include timely communication back to the prescriber.

In addition, the RACGP suggests the following:

- Include limits relating to patient eligibility, eg patients must be over 18 years and under 50 years of age, and non-smokers.

References

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[2] Transcript of press conference, 8 April 2021, available: www.pm.gov.au/media/press-conference-australian-parliament-house-act-08april21

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[9] Steenland MW, Rodriguez MI, Marchbanks PA, Curtis KM. How does the number of oral contraceptive pill packs dispensed or prescribed affect continuation and other measures of consistent and correct use? a systematic review. Contraception. 2013;87(5):605-610.

[10] Australian Bureau of Statistics. Patient experience in Australia: Summary of findings, 2019-20