Submission of Family Planning NSW

Public consultation on proposed amendments to the Poisons Standard (oral contraceptives)

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Therapeutic Goods Administration
Medicines Scheduling
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Family Planning NSW welcomes the opportunity to make a submission to the Therapeutic Goods Administration regarding the 'Public consultation on proposed amendments to the Poisons Standard (oral contraceptives)'.

About Family Planning NSW

Family Planning NSW is the leading provider of reproductive and sexual health services in NSW and Australia. We are experts in clinical service provision, including contraception, pregnancy options, STIs, sexuality and sexual function, menstruation, menopause, common gynaecological and vaginal health problems, cervical screening, breast awareness and men's and women's sexual health.

Our mission is to enhance the reproductive and sexual health and rights of our communities by supporting all people to have control over and decide freely on all matters related to their reproductive and sexual health. Our work is evidence-based and shaped by our research.

As an independent, not-for-profit organisation, we recognise that everybody in every family should have access to high-quality clinical services and information. Each year we provide more than 31,000 clinical occasions of service to clients, information and health promotion activities to communities, and best practice education and training in reproductive and sexual health for health professionals, educators and disability support workers. We have five fixed clinics in NSW and use innovative partnerships to deliver services in other key locations across the state.

Our services are targeted to marginalised and disadvantaged members of the community, including young people, people from culturally and linguistically diverse and Aboriginal and Torres Strait Islander backgrounds, and people with disability.

Family Planning NSW Medical Director, Adjunct Professor Deborah Bateson, is a recognised expert in contraception nationally and internationally and is a co-author of the current electronic Therapeutic Guidelines on Contraception and multiple clinical practice-based articles in the area of reproductive health.

Addressing equitable access to contraception in Australia

Reproductive and sexual health is an area where there is high unmet need, particularly in regard to equitable access to contraception. One approach to improve access to oral contraception would be through provision of oral contraceptives in community pharmacies by suitably trained pharmacists. Limited and/or no access to contraception contributes to rates of unintended pregnancy.

One in four Australian women have experienced an unintended pregnancy in the past decade. About half of these pregnancies occurred amongst women not using contraception, and about one third ended in abortion.(1)

In Australia, there is a 10.7% unmet need for family planning - when a woman wants to stop or delay childbearing but is not using contraception.(2) An unmet need for family planning has significant implications for women, their families and communities. Research shows that (3):

- firstborn children of mothers under the age of 18 are at the greatest risk of neonatal mortality, preterm birth, and infant mortality
- meeting women's need for contraception can have a large impact on maternal, infant and child deaths
- reducing fertility rates can improve infant survival, children's health, education and wellbeing, women's economic productivity and household income.

All women should have equitable access to contraception via skilled healthcare professionals. Increasing access to oral contraceptives, through suitably trained pharmacists, would likely improve access and, in particular, continuity of supply of oral contraceptives when scripts run out and women

cannot see their healthcare provider in a timely manner. Several studies suggest that oral contraception provided 'over the counter' may increase women's access to contraception, reduce unintended pregnancy and result in higher continuation rates.(4,5)

Our position

As experts in reproductive and sexual health, Family Planning NSW supports strategies to enhance access to oral contraceptives, provided these strategies take appropriate measures to ensure they do not inadvertently compromise patient safety, quality and contraceptive choice.

Family Planning NSW is broadly supportive of the proposed amendments in Application A and B, however, we have outlined our specific concerns with each application below which would need to be clearly addressed by the applicants. Family Planning NSW would like to strongly emphasise the importance of prescribers (medical practitioners and nurse practitioners), being the only health providers to initiate first dose of oral contraception, the need for a maximum supply quantity outlined within each application, and the implementation of a maximum time frame in which patients must see a prescriber to continue treatment.(6)

Quality and safety of pharmacist provision of continued oral contraceptives will be dependent on the quality of training and continuing professional development received, and on the governance of these processes. These issues, together with the need for supportive checklists and decision tools are discussed further below.

Family Planning NSW outlines the following specific concerns and areas for clarification in relation to Application A:

- Clarity is sought on the wording "authorised health professional" and whether this includes endorsed nurse practitioners.

- It is unclear whether this application is restricted to combined hormonal pills with progestogen and estrogen or if it also includes progestogen-only pills. Family Planning NSW would be broadly supportive of the application referencing both types of contraceptive pills.

- There is no detail regarding how many months' supply of the oral contraceptive may be provided by pharmacists at a single time. In line with Application B, 4-months would be a reasonable time frame.

- The maximum timeframes between prescriber reviews should be made clearer. While there is mention in the summary of the applicant's reason for proposal that "all patients must have had the same substance prescribed by an authorised health professional within the previous two years", there is no mention of this timeframe in Appendix M. The position of Family Planning NSW is to support continuing provision of oral contraceptives by suitably trained pharmacists, for up to 2-3 years between prescriber reviews.

- Clarity is lacking around how pharmacists will confirm previous prescriptions from authorised health professionals and provision by other pharmacists, including private prescriptions.

- Clarity is needed regarding whether a pharmacist would be able to re-initiate an oral contraceptive previously prescribed but not used continuously by a patient.

- Greater detail is needed on the provision, content, standards and governance of the "accredited training course" for pharmacists. Further information is required on plans for continuing professional development for pharmacists as well as supporting resources and documentation related issues.

Family Planning NSW outlines the following specific concerns and areas for clarification in relation to Application B:

- Clarity is sought on the wording "health professional" and "prescriber", and whether this includes endorsed nurse practitioners.

- The upper limit of an ethinylestradiol dose is not indicated in this application. Family Planning NSW recommends that the dose of ethinylestradiol should be limited to 35mcg given the unacceptable increased risks of venous thromboembolism (VTE) with 50mcg of ethinylestradiol.(7)

- Family Planning NSW does not recommend the inclusion of a pill containing mestranol as there is insufficient research in relation to the risk of VTE and this pill is very rarely prescribed in the Australian setting.

- It is unclear whether this application is restricted to combined pills with an estrogen and progestogen component or includes progestogen-only pills. Levonorgestrel is listed as needing to be combined with an estrogen, while norethisterone is not. Family Planning NSW would be broadly supportive of the application containing both types of contraceptive pills.

- Contraceptives containing cyproterone are only approved by the Australian TGA for use in individuals with hirsutism or severe acne. They provide effective oral contraception in these patients, however, their primary indication is not for contraception. Further, formulations containing cyproterone require careful exclusion of early pregnancy before starting, given theoretical risk of feminisation of a male fetus and a higher risk of VTE compared to pills with levonorgestrel. It is recommended that medical and nurse practitioners' consider switching off cyproterone acetate-containing pills once angrogenic symptoms have settled.(8)As such, Family Planning NSW does not support the continuing provision of cyproterone-containing pills by pharmacists.

- In Appendix M, there is the requirement that "a previous prescription from a health professional is confirmed". However, there is no indication as to an acceptable timeframe between the last prescription and pharmacist provision of an oral contraceptive. Patients' circumstances, medical comorbidities and risk factors change throughout the course of their life, which may affect a patient's preference or suitability for a given contraceptive. Family Planning NSW supports continuing provision of oral contraceptives by suitably trained pharmacists, for up to 2-3 years between prescriber reviews.

- In Appendix M, it recommends that "the person undergoes clinical review by a prescriber or pharmacist at least annually" but it is unclear what this review would constitute in the pharmacy setting. Overall, the nature and content of pharmacy reviews needs greater explanation to ensure the safe provision of continuing supply.

- Further clarification is needed regarding the meaning of "a person's therapy is stable". This phrase lacks clinical applicability in the context of contraceptive pills. The applicant needs to clarify what constitutes an interruption of therapy in Appendix M. Further, it is not clear why there is a restriction of pharmacist supply of oral contraceptives within 12 months of the person initiating therapy.

- Appendix M requirements for oral contraceptive dispensing listed in Application B, omit requirements for pharmacist training, accreditation and pharmacist dispensing. Application B instead refers to "approved pharmacists" and lists additional requirements for dispensing relating to: confirming previous prescriptions; confirming stable therapy; annual clinical

review; maximum quantity and; appropriate recording. This lacks the necessary detail needed to assess the quality of the application. Quality training and continuing professional development for pharmacists is needed to ensure safe and effective oral contraceptive provision. As such, training and continuing professional development for pharmacists should be mandatory.

Alongside our position, Family Planning NSW outlines the following key points in relation to pharmacist provision of oral contraceptives:

1. Pharmacist provision should not replace initial provision, care and follow up by approved prescribers (medical practitioners and nurse practitioners)

While Family Planning NSW supports increased access to oral contraceptives, we strongly assert that pharmacist provision should not replace the initial provision of oral contraceptives by authorised prescribers who are approved prescribers, nor the ongoing care and holistic follow up to address changing contraceptive needs and choice, and review of medical eligibility.

There are many benefits of the provision of oral contraceptives by prescribers, including the opportunity to review a patient's reproductive and sexual heath more broadly. This may include: a comprehensive assessment of a patient's risk of sexually transmissible infections as well as sexual health screening and prevention; identification and investigation of menstrual problems and other symptoms of reproductive illness; cervical cancer screening; considered risk of reproductive coercion; and, discussions regarding consent and respectful relationships.

Prescribers also have a role in supporting a patients' decision-making process around contraceptive options, while understanding medical eligibility and the options available for a given patient. For example, prescribers may facilitate discussion around other contraceptive options, including long-acting reversible contraception (LARC), which the patient may not have considered. Given the higher contraceptive efficacy of LARC as well as their cost-effectiveness, as highlighted in the National Women's Health Strategy 2020-2030, LARC methods are considered as a key strategy in preventing unintended pregnancy.(9) It is imperative that pharmacists are able to provide evidence-based information about LARC methods as well as rapid referral pathways to local providers for the insertion of IUDs and implants.

Provision of a continuing supply of oral contraceptives by pharmacists, without clear guidance on regular intervals in which a clinical review and assessment by a prescriber, may limit the opportunity for health professionals to facilitate supported decision making and provide information about LARC.

2. Development of a comprehensive training program for pharmacists is needed

In order to facilitate safe and effective supply of oral contraceptives for patients who are continuing contraceptive use, a comprehensive training framework must be developed, with professional practice standards and guidance implemented. It is essential that pharmacists are adequately trained, and have access to approved up-to-date checklists based on national guidelines, to determine if it is appropriate and safe to provide an ongoing supply of oral contraception to patients, or if the patient should be referred to an authorised prescriber for further assessment.

To date, there are no up-to-date continuing education programs or technical assistance tools for contraceptive counselling and dispensing for pharmacists in Australia. As potential providers of contraception services, pharmacists must receive training and demonstrate their competency to provide high quality and safe person-centred consultations. Training should include: screening for medical contraindications including drug interactions; measurement of blood pressure and BMI, provision of information regarding correct use of oral contraceptives and advice on missed pills; provision of information on potential side-effects and when to seek medical advice; ability to identify when referral back to a health professional is required, together with knowledge of referral

pathways; ensuring awareness of other contraceptive options, especially LARC; referring those with contraindications to the OCP and/or interested in alternative contraceptive methods to providers of these methods and; referring to an appropriate healthcare professional for health screening as necessary.

Family Planning NSW strongly recommends that a comprehensive training framework is developed and clearer guidance around governance and assessment of pharmacist competency provided. As experts in reproductive and sexual health, and co-authors of the current Electronic Therapeutic Guidelines on Contraception, we strongly recommend we are involved in consultation regarding the development and implementation of the training framework.

3. Additional considerations for pharmacists providing review and ongoing access to oral contraception

Ongoing supply determination and provision of information in a confidential space
As part of a comprehensive contraception consultation, in addition to providing oral contraceptives safely, health professionals provide patients with information on how to take the pill appropriately, how to manage missed pills to reduce pregnancy risk and where to go in case of follow up questions and/or concerns. These conversations must be conducted privately and confidentially.

With the requirement for pharmacists to determine if it is appropriate and safe to maintain ongoing supply of oral contraception, it is essential to ensure patient privacy. It is imperative that all pharmacists potentially undertaking this role have a private and welcoming space for the assessment of safe provision and contraceptive counselling. Pharmacist provision, should only occur when this space can be guaranteed.

Access to Pharmaceutical Benefits Scheme (PBS) subsidies
Multiple factors influence an individual's choice of an oral contraceptive pill including side-effects, non-contraceptive benefits (e.g., for acne and heavy menstrual bleeding) as well as cost. PBS subsidies support equitable access to oral contraceptives, as they ensure that people on a range of incomes have access as needed. The PBS-listed pills are first line but may not suit all women who are experiencing side-effects or desire non-contraceptive benefits from alternative non-subsidised options. Costs for these private pills can be prohibitive for some and details of the safeguards put in place to ensure women are accessing the most cost-effective option that meets their specific needs are required.

Notification regarding patient ineligibility for schedule 3 supply
There needs to be a clear mechanism in place where the prescriber can alert pharmacists that a patient is not eligible for pharmacy supply. This is to ensure higher risk patients such as those with Medical Eligibility Criteria 3 medical conditions, who while not contraindicated to the oral contraceptive pills, have risks which can outweigh the benefits provided by oral contraceptives and need close review by the prescriber.(10)

Conclusion

Provision of oral contraceptives, by suitably trained and credentialed pharmacists is likely to increase equitable access to oral contraceptives. However, in allowing this access to care there would need to be a number of safeguards in place to ensure it does not impact on patient safety, quality and contraceptive choice. While we broadly support these applications, consideration of the potential unintended losses to patient care with this model is needed. Family Planning NSW thanks the Committee for considering our questions for clarity in detail.

References

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