Submission of Family Planning NSW

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

November 2021

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 interim decisions to amend the Poisons Standard – November 2020 ACMS/ACCS meetings'.

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.

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.

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.

Our position

As experts in reproductive and sexual health, Family Planning NSW strongly 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.

We recognise the Delegate of the Secretary's decision to not amend the scheduling for oral contraceptives in response to Application A and B as they currently stand, however, we encourage the Therapeutic Goods Administration to prioritise exploration of strategies to enhance access to oral contraceptives via pharmacists that will ensure patient safety and quality of service delivery. Allowing continued access to oral contraceptives through pharmacies would allow greater contraceptive access for those who have difficulties returning to a General Practitioner, and thereby reduce risks associated with unintended pregnancy.

There is significant need to address barriers that prevent women from accessing contraceptives in primary healthcare settings, particularly for those in rural and regional areas who have reduced access to prescribing medical and nurse practitioners.

Alongside our position, Family Planning NSW outlines the following items in relation to the notice of the interim decision and pharmacist provision of oral contraceptives:

1. Response to the interim decision

Family Planning NSW would like to outline the following queries and areas for clarification in response to the interim decision:

- an increased risk of cervical cancer is listed as a risk (page 6), but reduced risk of endometrial, ovarian and colorectal cancer is not listed as benefits.(1) Additionally, the increased risk of breast cancer is not mentioned as a risk, however, there is mention of an increased risk of weight gain. There is no clear evidence for a causal association of oral contraceptives with weight gain.(1) It is important a comprehensive and evidence-based list of risks and benefits is presented.

- in mention of toxicity, the report states most oral contraceptives are not recommended for people who are breastfeeding. As per the recommendations of the Sexual and Reproductive Health Guidelines of the Royal College of Obstetricians and Gynaecologists and the Australian Electronic Therapeutic Guidelines, progestogen only pills are safe to use immediately following a delivery in breastfeeding women. Additionally, evidence available suggests that use of combined hormonal contraceptive pills in breastfeeding women, does not adversely affect breastfeeding performance nor infant outcomes, and are considered safe to use from 6 weeks postpartum, provided there are no other contraindications.(2, 3) We recommended the statement be clarified.

- under *reasons for the interim decision,* the report states "The use of oral contraceptive pills can cause significant adverse effects that are not consistent with over the counter medicines. These effects include weight gain, emotional anxiety, heavy bleeding and thromboembolism, particularly with increasing age." Family Planning NSW asserts the main clinical concern is venous thromboembolism (VTE). Combined (estrogen-containing) oral contraceptives are associated with 3 to 3.5 fold increased risk of VTE,(1) while progestogen-only pills are not associated with an increased VTE risk.(4) Robust pharmacist training and medical eligibility checklists would ensure women at increased risk of VTE are provided with safe contraceptive methods i.e. progestogen only and not combined oral contraceptives. We note that current evidence does not support a causal association between the use of oral contraceptives and mood disturbance or weight gain.(1) We also note that rather than causing heavy bleeding, the combined oral contraceptive pill is an evidence-based management approach for heavy menstrual bleeding. Provision for this reason should always occur within a GP/specialist consultation.

- under *any other matters that the Secretary considers necessary to protect public health*, the report states "Internationally, most [oral contraceptives] are only available as prescription only medicines, if approved for use at all. Exceptions are ethinylestradiol, levonorgestrel, norethisterone and desogestrel, which are available as over the counter medicines in New Zealand in certain limited contexts." Pharmacist provision, with or without initial prescription by a medical or nurse practitioner, also occurs in the United States, Canada, Netherlands, Quebec and the United Kingdom. We recommend this statement be clarified to not assume that only New Zealand offer pharmacist provision of oral contraceptives.

- we are concerned that the decision does not recognise the different level of risk between combined (estrogen-containing) oral contraceptives and progestogen only pills (specifically pills that only contain levonorgestrel or norethisterone/norethindrone), as well as the comments about the need for a GP visit to encourage use of LARC. This approach typically only focuses on the efficacy of a contraceptive method and limits patient autonomy.

2. Enhancing access to oral 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 continued provision of oral contraceptives in community pharmacies by suitably trained pharmacists. Limited and/or no access to contraception contributes to rates of unintended pregnancy.

Despite availability of contraception, there is an 8% unmet need for family planning in Australia,(5) with women in outer metropolitan, rural and regional areas experiencing greater disadvantage in regard to access to contraceptive services. In rural and regional areas, the ability to easily access primary care services and contraception can be limited.(6)

For women who find returning to their initial prescriber difficult, allowing continuing provision of contraceptive pills by pharmacists may improve contraceptive accessibility and convenience. Pharmacies typically have longer opening hours than GPs, convenient locations and provide a walk-in service without appointment. Rescheduling of select oral contraceptives, with the appropriate safety and quality considerations put in place, ensures women have greater access to oral contraception should their prescribed supply run out. 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.(7, 8)

For enhanced access via pharmacist provision to occur, the following considerations must be addressed to ensure quality and safe provision:

- development of a comprehensive credentialed training program and framework for pharmacists

- requirements for private spaces for assessment to allow safe provision and contraceptive counselling (pharmacist provision should only occur when this space can be guaranteed)

- 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 conditions, who while not absolutely contraindicated to the oral contraceptive pills, have risks which can outweigh the benefits provided by oral contraceptives and need close review by the prescriber)

- clear communication framework in place where pharmacists can inform prescribers when clients have accessed a continuing supply of their prescribed oral contraceptive.

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

While Family Planning NSW strongly supports increased access to oral contraceptives, we strongly assert that pharmacist provision should not replace the initial provision of oral contraceptives by authorised prescribers, nor the ongoing care and holistic follow up to address changing contraceptive needs and choice, and review of medical eligibility. We also support requirements for communication frameworks and pathways between the prescribing medical practitioner and pharmacist to ensure continuity of care.

Conclusion

Provision of oral contraceptives, by suitably trained and credentialed pharmacists is likely to increase equitable access to oral contraceptives. 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.

Family Planning NSW is broadly supportive of the proposed applications if the necessary safeguards could be put in place. We encourage the Therapeutic Goods Administration to prioritise exploration of strategies to enhance access to oral contraceptives via pharmacists that will ensure patient safety and quality of service delivery. Pharmacist provision is an opportunity to enhance women's access to contraception, particularly in areas of unmet need.

References

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2. Faculty of Sexual and Reproductive Healthcare. FSRH Clinical Guideline: Contraception After Pregnancy (January 2017, amended October 2020). England: FSRH; 2020.

3. Therapeutic Guidelines. Sexual and Reproductive Health: Contraception. Melbourne: Therapeutic Guidelines Limited; 2021.
4. Healthcare FoSaR. FSRH Clinical Guideline: Progestogen-only Pills (March 2015, Amended April 2019). England: FSRH; 2019.
5. United Nations Population Fund. The state of world population 2020. New York; 2020.
6. Newman P, Morell S, Black M, Munot S, Estoesta J, Brassil A. Reproductive and sexual health in New South Wales and Australia: differentials, trends and assessment of data sources. Sydney; 2011.
7. Kennedy CE, Yeh PT, Gonsalves L, Jafri H, Gaffield ME, Kiarie J, et al. Should oral contraceptive pills be available without a prescription? A systematic review of over-the-counter and pharmacy access availability. BMJ Glob Health. 2019;4(3):e001402-e.
8. Gardner JS, Downing DF, Blough D, Miller L, Le S, Shotorbani S. Pharmacist prescribing of hormonal contraceptives: Results of the Direct Access study. Journal of the American Pharmacists Association. 2008;48(2):212-26.