Department of Health

Therapeutic Goods Administration

Proposed amendments to the Poisons Standard in relation to substances when used in oral contraceptives – ACMS #34, June 202

Consultation Response

May 2021

Submitted via medicines.scheduling@health.gov.au.

Acknowledgement of Country

Marie Stopes Australia acknowledges the Traditional Owners and Custodians of the land on which we live and work. We pay our respects to Aboriginal and Torres Strait Islander Elders past, present and emerging.

We also acknowledge the enduring connection to their Traditional estates across Australia and to the ongoing passion, responsibility and commitment to and for their lands, waters, seas, flora and fauna as Traditional Owners and Custodians.

Published by
Marie Stopes Australia (Marie Stopes International)
GPO Box 1635, Melbourne VIC, 3001

Proposed amendments to the Poisons Standard in relation to substances when used in oral contraceptives: consultation response

Further information

[redacted]

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Executive Summary

These applications would increase sexual and reproductive health access and equity in metropolitan, regional and remote areas of Australia. On merit, we support Application A, and Application B with caution regarding cyproterone, in the context of the following specific recommendations.

Policy recommendations are:

- Further define contraceptive care models in pharmacy settings to ensure holistic and culturally safe care.
- A compulsory system of training and certification for pharmacists with mandatory completion of regular clinical updates[1] accompanied by;
    - Professional Practice Standards and the development and implementation of appropriate technical assistance tools for dispensing OCPs and;
    - accountability by the organisations responsible for developing the pharmacist training program, technical assistance tools and Professional Practice Standards.
- Develop baseline, monitoring and evaluation mechanisms to ensure safety and quality of care, and to measure the impacts of this delivery model.
- Ensure oral hormonal combined contraceptives are prescribed according to the Medical Eligibility Criteria which is an evidence-based, internationally recognised tool enabling safe and appropriate contraceptive prescribing.[2]
- Invest in accessible health literacy resources that share the actual efficacy of all contraceptive methods, to promote informed contraceptive choices, such as: www.contraception.org.au.[3]

Practice recommendations are:

- Ensure prescribers follow evidence-based guidelines and medical eligibility criteria to support safe prescribing.[4]
- Ensure accurate advice for people who are breastfeeding including all available contraceptive options and not just the progestogen only oral contraceptive pill which has lower efficacy than many other available options
- Pharmacists should explore and dispel contraceptive myths and misinformation on contraceptive choices, to ensure people have accurate information to enable them to make an informed choice
- Incorporate consultation considerations listed within this submission, including consideration of how to signpost for holistic sexual and reproductive health care including STI and cervical screening.
- Ensure all people working in pharmacy settings have the skills and resources to prevent and respond to reproductive coercion.[5]

At Marie Stopes Australia we welcome pharmacists to have a more prominent role in our client support and referral networks. We look forward to ongoing collaboration for bodily autonomy and reproductive justice in Australia.

Introduction

The Australian Government Department of Health Therapeutic Goods Administration (TGA) has a current consultation open in regards to over the counter oral contraceptive access. The consultation is in relation to two private applications to 'down-schedule substances when used in oral contraceptive pills from Schedule 4 to Schedule 3, subject to proposed Appendix M controls'.[6]

In May 2021 the Therapeutic Goods Administration invited public submissions. This submission has been structured in response to the two separate applications, followed by concluding remarks on both applications.

Background

As an independent, non-profit organisation, Marie Stopes Australia is Australia's only national accredited provider of abortion, contraception and vasectomy services, and the country's longest running provider of teleabortion. Our holistic, client-centred approach empowers individuals to lead their own reproductive healthcare safely, and with dignity, regardless of their circumstances. Through active partnerships with healthcare providers, researchers and communities, our models of care ensure the total wellbeing of our clients is supported at every stage.

We provide clinical care to thousands of Australians, residents and people who are temporary visa holders in Australia each year. [7] Each year we receive approximately 175,000 enquiries and provide 50,000 sexual and reproductive health clinical services. On average, 1 in 10 of those services are provided without access to Medicare.

Item 1.1 - Application A (3 substances, Items 2.1, 2.2 and 2.3)

Item 2.1 - ethinylestradiol

Item 2.2 - levonorgestrel

Item 2.3 - norethisterone

With clinical guidance and established safety and quality measures, this proposal would increase contraceptive access and equity in Australia. The provision of progestogen-only contraceptive pill in Australian pharmacies is in line with international evolving models of care.[8]

It is reassuring to see all methods in this application have the same criteria.

Competency via the Pharmaceutical Society of Australia is critical. Training should be incorporated into pre-service tertiary education. Prescriber certification should be reviewed at regular intervals.

Evidence of previous prescriptions within the last 2 years should be assessed alongside a private consultation that considers:

- the patient's medical history since those prescriptions were issued, and specifically identification of contraindications and cautions for the use of combined hormonal contraception for example migraine headaches and venous thromboembolism, which may indicate a change in medical eligibility category for the chosen method
- measurement of blood pressure and Body mass index (BMI)
- provision of patient information on all contraceptive choices, including the more efficacious Long Acting Reversible Contraception options and where to access these
- opportunities for sexually transmitted infection (STI) screening and treatment
- opportunities for cervical screening
- screening or sensitive enquiry to prevent and respond to risk of reproductive coercion, and
- if referral to contraceptive choices counselling is required,

Providing these and other relevant safeguards are in place and monitored, we support Application A.

Item 1.2 - Application B (11 substances, Items 2.1 to 2.11)

Item 2.1 - ethinylestradiol

Item 2.2 - levonorgestrel

Item 2.3 - norethisterone

Item 2.4 - cyproterone

Item 2.5 – desogestrel

Item 2.6 – dienogest

Item 2.7 – drospirenone

Item 2.8 – estradiol

Item 2.9 – gestodene

Item 2.10 – mestranol

Item 2.11 – nomegestrol

The recommended first choice of Combined Oral hormonal Contraceptive (COC) is a pill containing ≤30mcg of ethinylestradiol combined with levonorgestrel or norethisterone,[9] which are both listed in Application A.

The newer progestogens listed in Application B are generally not prescribed first line due to the higher (or yet unquantified) venous thromboembolism risk.[10] Additionally they are more expensive because COCs containing the progestogens drospirenone, desogestrel, dienogest, gestodene or nomegestrol are not PBS listed.

Cyproterone acetate is an anti-androgen indicated for the treatment of women with severe acne, with associated symptoms of androgenisation, including seborrhoea and mild hirsutism. Cypeoterone acetate containing pills are and are not indicated for women who desire contraception who do not have co-morbid hyperandrogenism. We therefore do not support Item 2.4 in Application B.

We offer support to the intent of Application B, adding similar caveats to that of Application A, however we strongly suggest caution to any inclusion of cyproterone.

Analysis

Sexual and reproductive healthcare in Australia is far from accessible or equitable. The National Women's Health strategy (2020-2030) calls for increased contraceptive uptake, yet investment towards and measurements of these measures remain unclear.[11] In the pandemic context we have witnessed barriers to contraceptive choices increase.[12] In addition to supply chain issues, we are facing a global healthcare worker skills shortage. Evolving models of care, extended scope of care, and greater collaboration within our health systems is the only way in which we can solve these ongoing issues of access and equity. This includes evolving models of care within pharmacy settings.[13]

These applications would change the way in which people access contraceptive methods in Australia. A similar historic moment was when emergency contraception moved to over the counter access. While implementation has been effective,[14] when this occurred we saw decreased uptake of the Copper IUD as an emergency contraceptive method. Given that oral contraceptives have lower efficacy than Long Acting Reversible Contraception,[15] we would want this application to increase greater uptake of contraception overall rather than decreased uptake of Long Acting Reversible Contraception. Subsequently, it is critical that contraceptive health information and advice always includes non-judgemental references to every contraceptive choice.

A trained clinician, such as a GP, sexual and reproductive doctor or nurse practitioner is best placed to navigate reproductive health needs in the context of holistic care. In order to increase access to contraception we support repeat prescriptions from pharmacies of drugs in Application A and B with safeguards in place and monitoring of these in accordance with a specified protocol and additional Appendix M requirements, when there is evidence of a prescription within the previous two years (application A) or one year (Application B)

Contraceptive consultations in clinical settings include broader sexual and reproductive health screening, offering opportunities for holistic health and wellbeing. Translating contraceptive consultations to pharmaceutical settings would need to justify how these broader health outcomes would be maintained. Similarly, pharmaceutical settings would also need to enable private spaces for health literacy,

screening and sensitive inquiry, mental health support and referral. Pharmaceutical settings need to be co-designed with health consumers to create spaces conducive of privacy, trauma informed care and cultural safety.[16]

Recommendations

Policy recommendations are:

- Further define contraceptive care models in pharmacy settings to ensure holistic and culturally safe care.
- A compulsory system of training and certification for pharmacists with mandatory completion of regular clinical updates[17] accompanied by;
    - Professional Practice Standards and the development and implementation of appropriate technical assistance tools for dispensing OCPs and;
    - accountability by the organisations responsible for developing the pharmacist training program, technical assistance tools and Professional Practice Standards.
- Develop baseline, monitoring and evaluation mechanisms to ensure safety and quality of care, and to measure the impacts of this delivery model.
- Ensure oral hormonal combined contraceptives are prescribed according to the Medical Eligibility Criteria which is an evidence-based, internationally recognised tool enabling safe and appropriate contraceptive prescribing.
- Invest in accessible health literacy resources that share the actual efficacy of all contraceptive methods, to promote informed contraceptive choices, such as: www.contraception.org.au.[18]

Practice recommendations are:

- Ensure prescribers follow evidence-based guidelines and medical eligibility criteria to support safe prescribing.[19]
- Ensure accurate advice for people who are breastfeeding including all available contraceptive options and not just the progestogen only oral contraceptive pill which has lower efficacy than many other available options
- Pharmacists should explore and dispel contraceptive myths and misinformation on contraceptive choices, to ensure people have accurate information to enable them to make an informed choice
- Incorporate consultation considerations listed within this submission, including consideration of how to signpost for holistic sexual and reproductive health care including STI and cervical screening.
- Ensure all people working in pharmacy settings have the skills and resources to prevent and respond to reproductive coercion.[20]

Providing the above measures are incorporated into evolving models of care, we offer our support and collaboration in progressing over the counter access to oral contraceptive choices.

Conclusion

These applications would increase sexual and reproductive health access and equity in metropolitan, regional and remote areas of Australia. On merit, we support Application A, with caution to specific issues and recommendations listed above. We offer support to the intent of Application B however caution risk associated with specific medications. In particular, we recommend that cyproterone be either excluded or only be retained with significant caution.

We would welcome pharmacists to have a more prominent role in our client support and referral networks. We look forward to ongoing collaboration for bodily autonomy and reproductive justice in Australia.

References

[1] Recommendation adapted from SPHERE coalition discussions.

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[3] Marie Stopes Australia (2021), Contraception, viewed 20 May 2021 at https://www.contraception.org.au/

[4] World Health Organization. (2018). Implementation guide for the medical eligibility criteria and selected practice recommendations for contraceptive use guidelines: a guide for integration of the World Health Organization (WHO) Medical eligibility criteria for contraceptive use (MEC) and Selected practice recommendations for contraceptive use (SPR) into national family planning guidelines.

[5] Marie Stopes Australia (2020), Hidden forces: a white paper on reproductive coercion in contexts of family and domestic violence, second edition, viewed 20 May 2021 at https://www.mariestopes.org.au/advocacy-policy/reproductive-coercion/.

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[13] The Faculty of Sexual and Reproductive Healthcare (2020) FSRH Consultation Response: FSRH supports NICE Quality Standards for Community Pharmacies at https://www.fsrh.org/news/fsrh-consultation-response-nice-community-pharmacies/

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[16] Goodrich, J. (2018). Why experience-based co-design improves the patient experience. *The Journal of Health Design*, *3*(1).

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[18] Marie Stopes Australia (2021), Contraception, viewed 20 May 2021 at https://www.contraception.org.au/

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[20] Marie Stopes Australia (2020), Hidden forces: a white paper on reproductive coercion in contexts of family and domestic violence, second edition, viewed 20 May 2021 at https://www.mariestopes.org.au/advocacy-policy/reproductive-coercion/.