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AMA Submission to the Therapeutic Goods Administration – Proposed amendments to the Poisons Standard – June 2021 – oral contraceptives

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The following submission refers to the proposed amendments to the Poisons Standard to be considered by the Advisory Committee on Medicines Scheduling (ACMS) #34 meeting, June 2021. The AMA has provided a separate submission to the proposals relating to amygdalin and hydrocyanic acid, bufexamac, and ibuprofen, to be considered at the same meeting.

Introduction

The AMA vehemently opposes both applications to downschedule oral contraceptive pills (OCPs) from Schedule 4 (prescription only) to Schedule 3 (pharmacist only). The AMA believes this change would have a detrimental impact on quality and safe care provided to patients being prescribed or seeking a prescription for an OCP.

The AMA does not believe, as the applicants state, this downscheduling would strengthen primary health care or improve public health. This proposal would instead fragment health care by striving to exclude the patient's usual GP from involvement in their patients' sexual, reproductive, and overall health. GPs provide a holistic service to patients who seek an OCP prescription, including engaging in preventative care and ensuring the OCP is suitable for the patient, including whether the benefits of taking an OCP outweigh the risks.

Patient safety

Taking oral contraceptives is not without risks.

The side effects of OCPs can be life threatening. These include blood clots, stroke and heart attacks, all of which are exacerbated if patients are smoking and/or overweight. Increasing age also increases the risk of adverse outcomes. Taking a combined OCP when the patient has thrombophilia can increase the risk of venous thrombosis up to sevenfold (however this risk could be higher)[1], representing a contraindication to prescription of the combined OCP. Approximately one third of patients of European origin with venous thromboembolism have heritable

[1] Vlijmen, E et al (2016) *Combined oral contraceptives, thrombophilia and the risk of venous thromboembolism: a systematic review and meta-analysis.* Journal of thrombosis and haemostasis.

thrombophilia, and the risk is higher in people below 50 years old[2]. Some contraindications develop over time in a way that would not be identified by a pharmacist.

Risks will increase as there is less opportunity in a pharmacy setting to undertake a full patient history and examination looking for range of medical illnesses which may not yet be apparent. A full assessment includes identifying interactions with other medicines, such as antibiotics, anticonvulsants, and anticoagulants, that may interfere with the effectiveness of OCPs.

Pharmacists are also not adequately trained to prescribe OCPs and do not practice in a suitable environment to allow private, comprehensive discussions with the patient. Pharmacies are set up as a retail, public environment and are therefore not appropriate settings to discuss a patient's medical history or the issues above. Pharmacists have also indicated that they lack the time to conduct proper patient assessments in health check program trials[3].

The AMA considers the high number of adverse events reported in the consultation paper to be an example of why these medicines should be monitored by a medical practitioner. The AMA particularly notes the 'TGA prescribing medicines in pregnancy database' categories for some OCPs as category D – where there is an increased incidence of human foetal malformations or irreversible damage, and the potential for adverse pharmacological effects.

Oral contraceptives may be supplied by pharmacists for reasons other than contraception, posing a risk to patients.

It is important to note that patients also use OCPs for medical conditions such as endometriosis, bleeding disorders, period pain, and acne[4]. Pharmacists will not be able to assist patients with prescribing OCPs if the patient has other reasons for needing the medication. This is due to scope of the proposal and because they are not medical practitioners who are suitably trained to diagnose and prescribe for these conditions.

Patients experiencing problems with their menstrual cycles, such as painful heavy bleeding, may self-diagnose the need for an OCP to provide symptom relief. However, OCP use in these circumstances can delay diagnosis and as such may increase future fertility problems. Endometriosis, a common condition affecting around 11 per cent of women, has a 7-12 year delay in diagnosis following commencement of symptoms such as heavy and painful periods[5]. Approximately 30 per cent of patients with endometriosis have infertility issues[6]. Bypassing examination by a suitably qualified medical practitioner may further delay diagnosis and treatment leading inevitably to an increased demand for future fertility treatments including the very expensive and invasive IVF treatment.

[2] Ho, WK et al. (2011) *Should adult patients be routinely tested for heritable thrombophilia after an episode of venous thromboembolism?* Medical Journal of Australia
[3] NSW Health (2017) *NSW Pharmacy health check program.*
[4] Better Health Channel (2019) *Contraception – the combined pill.*
[5] Endometriosis Australia (2020) *What is endometriosis?*
[6] Jean Hailes (2019) *Endometriosis and fertility.*

There is a risk that patients may either fail to inform the pharmacist that their reasons for seeking these medicines is for cycle control or pain relief rather than contraception, or they may pressure pharmacists to supply OCPs despite the risks involved.

Alternative contraception methods may be safer, more effective and/or more appropriate

There are alternatives to OCPs which are safer and more effective. Long-acting reversible contraceptives are often the better choice for women seeking safe and effective contraception. Intrauterine devices and implants are the most effective contraceptive[7]. OCPs can also have side effects such as weight gain and mood changes[8] that may impact the patient's health and wellbeing to a point where prescribing the OCP is not appropriate.

Patients should have the opportunity to make a fully informed decision about the options available to them based on their medical situation and individual circumstances. Pharmacists will not be able to fully discuss, much less offer, all these options.

GPs provide holistic, high quality care to patients

It is internationally recognised that GPs are the cornerstone of a successful primary healthcare system, and countries with a strong general practice have better health outcomes[9]. Almost 85 per cent of patients see a GP each year and GPs remain the most common health service professional visited[10]. Fragmentation of care is becoming more common as health system pressures grow. Poorly coordinated patient care within the health system and inadequate links between health and social services results in poorer health outcomes and increased health care costs[11]. Ill-considered cost reduction strategies, like task substitution of non-medical health professionals for GP-led patient care, are increasingly proposed as a solution to these pressures. However, this further fragments patient care and results in poorer health outcomes and increased costs long-term[12]. The TGA must ensure that scheduling decisions support evidence-based primary care instead of creating unintended consequences from downscheduling medicines.

Prescribing an OCP can be complicated and it can take a while for medical practitioners and the patient to find the most suitable option. It requires an initial, and then episodic, consultation(s) by a medical practitioner to assess whether it is appropriate to start, continue, change or even cease an OCP and replace it with another contraceptive option[13]. Decisions to continue, monitor, change or cease contraception are complex and should involve longitudinal shared-decision making between the patient and their doctor. Medical practitioners will write prescriptions and repeats depending on when they need to review the patient. The timing between reviews is

[7] Health Direct (2019) *Contraception options.*
[8] Health Direct (2021) *The pill (combined oral contraceptive pill)*
[9] The World Health Organisation (2008) *The World Health Report 2008 - primary Health Care (Now More Than Ever).*
[10] Australian Bureau of Statistics (2020) *Patient experience in Australia: summary of findings.*
[11] Frandsen BR, et al (2015) *Care fragmentation, quality, and costs among chronically ill patients*. Am J Manag Care 2015;21:355–62
[12] Australian Medical Association (2020) *Delivering better care for patients: the AMA 10-year framework for primary care reform*.
[13] Moore and Streeton (2017) *Oral hormonal contraception in special circumstances.*

dependent on the patient and their condition and should be determined by a medical practitioner and not a pharmacist who has no knowledge of their complex medical history.

GP consultations for OCPs rarely involve just writing a prescription. A pilot study involving a survey of 104 GPs in the ACT found that 96 per cent of GPs diagnosed a secondary health issue when an OCP was prescribed[14]. Consultations typically involved discussions around the patient's wider, detailed, medical and social history, mental health, contraception alternatives, preventative health care such as cervical screening, blood pressure checks, and STI checks. The AMA is concerned that if the holistic care a GP provides is further fragmented by pharmacist prescribing of OCPs, other medical conditions might be missed and go unresolved.

Patient access to oral contraceptives and cost

The proposal does not provide sufficient evidence to back the claim that a Schedule 3 listing would increase safe, appropriate access to OCPs.

Any health system 'savings' would only be short-term as they are likely to be undermined by a reduction in preventive health care provided by GPs and subsequent downstream costs resulting from later presentations of established illness.

GPs are able to supply a patient with up to 12 months-worth of OCP on the prescription (if it is suitable for the patient), with the opportunity for patients to attend the GP whenever they need to before the 12 month mark to discuss their health. The AMA believes that a patient visiting their GP once a year for a new prescription is not an unreasonable requirement, nor would it inhibit access to OCPs. With the introduction of expanded telehealth items and electronic prescribing, doctors are available now more than ever before. GPs have practice arrangements in place to see patients who urgently need a consult for a script. In 2020, 72.1 per cent of patients who saw a GP for urgent care waited less than 24 hours[15].

Pharmacists already have options that allow them to provide access to medications in urgent or emergency circumstances and there are no good reasons to go beyond these, particularly as it impacts on the safety of care for patients and undermines the medical home model of care that is widely supported.

It is reasonable to assume that pharmacists would charge patients for a consultation/clinical review to determine whether the patient is suitable for OCPs, as this already occurs in pharmacies[16]. However, even if this one-off consultation happens to be cheaper than a GP visit, in the long run may end up being more expensive and patients receive less value for money.

Pharmacy consultations are not covered by the Medicare Benefits Schedule, while GPs can bulk-bill patients especially if cost is a barrier to receiving care. For the year to date up to December

[14] Donohue et al (2021) *The general practitioner contraceptive appointment. More than just a script?*. Not published.
[15] Productivity Commission (2020) *Report on government services 2020 – Primary and community health.*
[16] For example, Capital Chemist (2016) *Heart health check.* TerryWhite Chemmart (2019) *Health check.*

2020, 89.3% of GP services were bulk billed[17]. Pharmacists would also not be able to provide Pharmaceutical Benefits Scheme-subsidised OCPs.

Both applications state that the OCP being prescribed by pharmacists would only allow for a four months supply, while medical practitioners are currently able to prescribe a 12 months supply. This indicates that OCPs are accessible to patients in greater quantities if the prescription is provided by a medical practitioner and many patients would need to have a pharmacist consultation more often than a GP consultation. Further, a pharmacist consultation may result in the need for the patient to visit a doctor anyway if the pharmacist cannot adequately resolve the patient's medical issues, increasing the cost further. As a result, patients may end up paying more for the OCP if they go via the pharmacist prescribing pathway.

Prescribing pathways in Australia

The Pharmacy Board of Australia reviewed their position on pharmacist prescribing in 2019 and determined that pharmacists are not adequately qualified for autonomous prescribing[18], which clearly indicates that these downscheduling proposals are not suitable.

The AMA believes these applications attempt to bypass the national inter-governmental arrangements to determine the appropriate endorsement of scheduled medicines for non-medical health practitioners[19]. These arrangements ensure nationally consistent approaches to prescribing by non-medical health practitioners that are transparent, robust and informed by evidence. They also ensure common standards across professions for training and clinical practice, and support the safe and effective use of prescription medicines. Any expansion of non-medical practitioner prescribing should only occur within this national framework.

Conflicts of interest

The AMA is concerned about the conflicts of interest inherent in not separating prescribing and dispensing. Pharmacists would gain a direct financial benefit from prescribing OCPs which may bias their decision to prescribe without fully assessing patient suitability, their needs, and the risks and side effects of the medication. A 2019 study[20] of 205 Brisbane pharmacies reported a high rate of overtreatment and overselling against practice standards and guidelines (noncompliant treatment) for emergency hormonal contraception and medication for conjunctivitis. Only 57.6 per cent of pharmacies followed dispensing protocol and 31.3 per cent of pharmacies had overtreatment or overselling of medication reported. Clearly, there are still significant concerns around the lack of adequate pharmacist training, compliance, and methods to manage conflicts of interest.

[17] Department of Health (2021) *Medicare bulk billing rates continue to grow.*
[18] Pharmacy Board of Australia (2019) *Pharmacist prescribing – position statement.*
[19] Australian Health Practitioner Regulation Agency (2016) *Endorsement for scheduled medicines.*
[20] Smith, H et al (2019) *Pharmacist compliance with therapeutic guidelines on diagnosis and treatment provision.* JAMA.

Appendix requirements

Appendix H

OCPs should not be advertised. The AMA continues to be opposed to relaxing regulation around medicines advertising for Schedule 3 products. Direct to consumer advertising of medicines may increase use, but not necessarily effective or rational use in line with quality use of medicines principles. While advertising may potentially increase awareness of certain health conditions and medicines, its primary purpose is to increase demand and sales for the advertiser's product. Advertising to the public is about profits, not improving patient care.

Appendix M

The AMA has concerns around whether Appendix M compliance will be monitored.

How would the pharmacist accurately determine whether the patient has been prescribed the medication in the past? Patients may claim they have received the OCP in the past however the only reliable way to confirm this would be to contact the prescribing medical practitioner. Initial supply of a prescription medicine does not provide pharmacists with the full picture of the patient's medical health. Initial supply may have been provided however the medical practitioner may have discontinued the prescription and provided an alternative if the OCP did not suit the patient.

It is also unclear how the pharmacist will assess the suitability of the patient to allow safe and appropriate prescribing and dispensing of an OCP. Will the pharmacist take blood pressure and only go through a questionnaire? This will not be an appropriate method. Will the pharmacist provide follow up and long-term monitoring to ensure the OCP they prescribed is still suitable for the patient? Follow up is an essential requirement to ensure safe and appropriate prescribing of OCPs.

'Harmonising' regulation with other countries

The AMA notes that applicant B perceives harmonisation with New Zealand scheduling as a reason to downschedule OCPs. However, there are several OCPs proposed to be downscheduled that are not available through a New Zealand pharmacist and remain prescription only. The AMA also notes that other countries such as the USA, Canada, and Ireland have kept OCPs prescription only.

Conclusion

The AMA opposes the applications to downschedule OCPs on the basis that it will significantly impact patient safety and quality of care, impact public health and fragment primary care.

Medical practitioners place a high value on the professional role of pharmacists and work with them to improve the medication management of patients and their clinical outcomes. However, downscheduling OCPs will allow pharmacists to operate autonomously without acknowledging and examining the effect it will have on fragmentation of care, patient outcomes and quality of prescribing.

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