[redacted]

5 May 2016

Medicines Scheduling Secretariat
Therapeutic Goods Administration
medicines.scheduling@tga.gov.au

Proposal: To amend the existing Schedule 4 entry for ulipristal and create a new Schedule 3 entry to allow for emergency post-coital contraceptive use.

Chairperson, Medicines Scheduling Secretariat

[redacted]

Emergency contraception is an important component of the suite of contraceptive measures available to Australian women to reduce unintended pregnancy, and we were pleased to see ulipristal acetate ([redacted]) approved for use in Australia last month.

We welcome the opportunity to comment on the proposal to reschedule ulipristal acetate from a Schedule 4 Prescription Only Medicine to Schedule 3 Pharmacist Only Medicine.

We understand that the safety and ease of use of ulipristal acetate is comparable with that of levonorgestrel, which is a Schedule 3 Pharmacist Only Medicine and we believe it meets the requirements for a Schedule 3 listing outlined in the Australian Health Minister's Advisory Council (AHMAC) Scheduling Policy Framework for Medicines and Chemicals. In addition, we are informed that this medication is available extensively around the world including without a doctor's prescription in at least 25 European countries.

We understand that while ulipristal acetate can be used up to five days after unprotected intercourse, that its efficacy is highest, and in fact higher than that of levonorgestrel, in the first 24 hours after intercourse.

Given that this medication is more efficacious the sooner it is taken, particularly if a woman is due to ovulate within a day or two of intercourse, we feel it is imperative that any unnecessary barriers to access be removed.

The current prescription only classification represents a potential barrier and certain delay in accessing this medication in a timely manner, particularly for women in situations where seeing a General Practitioner is difficult or expensive.

This can be for a number of reasons including; lack of childcare, a controlling or abusive partner, geographical distance from healthcare services, a lack of service provision after hours, on weekends or public holidays, privacy concerns where the woman may not wish to see her regular General Practitioner or where the only accessible General Practitioner is known to be conservative, religious, judgemental or for other reasons unwilling to prescribe emergency contraception.

Similar issues can apply to finding a local pharmacy which stocks and dispenses the medication, however a number of online pharmacy services are available which offer phone consultations before dispensing and posting medication.

We support the application to reschedule ulipristal acetate to Schedule 3 Pharmacist Only Medicine.

Yours sincerely

[redacted]

28 April 2016

Medicines Scheduling Secretariat
Medicines Scheduling
Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606

To whom it may concern

Please find attached a submission from [redacted] to support the rescheduling of ulipristal acetate (UPA) - [redacted] for emergency contraception by [redacted] from Schedule 4 to Schedule 3.

Yours sincerely

[redacted]

[redacted]

Medicines Scheduling Secretariat,
Medicines Scheduling
Therapeutic Goods Administration
Department of Health
PO Box 100
Woden
ACT 2606
Australia

April 28th, 2016

To whom it may concern,

[redacted] enthusiastically supports the rescheduling of ulipristal acetate (UPA) - [redacted] for emergency contraception (EC) by [redacted] from Schedule 4 to Schedule 3.

Access to emergency contraception

Since the availability of LNG as a Schedule 3 emergency contraceptive pill (ECP) product in 2004, potential users know that the main point of access to EC is from pharmacies with a pharmacist consultation without the need to obtain a doctor's prescription. It is also available at some sexual health clinics and some hospitals. Prior to 2004, from the late 1970s, off-label use of a combined oral contraceptive pill [redacted] and then between 2002 and 2004, a dedicated EC product, [redacted], levonorgestrel (LNG) EC was available only on prescription.

Rescheduling EC to Schedule 3 has significantly improved access to the ECP in Australia (Calabretto 2012). The broad geographical locations and opening hours of community pharmacies means that access to EC in a timely manner is facilitated for women who have had unprotected intercourse (contraceptive failure or non-use, or sexual assault) and who do not wish to become pregnant. Prior to 2004, the need for a doctor's prescription, as well as other barriers, often made it difficult for women to obtain EC in a timely fashion. For some women, this meant not taking EC (which would have been their preference had it been easier to obtain), and waiting to see if they were pregnant (Calabretto 2005). The need for women to obtain UPA EC following a consultation with a doctor also has the potential to restrict its use. It can be difficult to arrange a doctor's appointment for women who have transport or financial issues (Calabretto 2005). Additionally, they may not feel comfortable approaching a GP in this situation. This can particularly be the case for young women who may have concerns about admitting to sexual activity, fears about confidentiality and parents being informed, and embarrassment about making appointments. Provision of UPA EC in addition to LNG EC in pharmacies will promote easier access for women of all ages.

Since 2004, pharmacists have demonstrated their ability (using guidelines from their professional body), the Pharmaceutical Society of Australia (2015) to provide women with EC. A common argument against rescheduling of LNG EC to Schedule 3 in 2002, was a concern that there would be lost opportunities for GPs to provide information to their patients about more effective, longer-term contraceptive methods if EC was available without prescription in pharmacies. This is an erroneous argument, given that under the requirements of Schedule 3, pharmacists are required to provide an

assessment of the need for EC, comprehensive information about the medication and when appropriate, referral to other services. Pharmacists are well placed to encourage users of ECPs to initiate or continue a more effective ongoing method of contraception. Additionally, they are aware of the GPs and sexual health clinics in their local areas as places for referral for contraceptive advice. At the time of rescheduling of LNG EC, pharmacists received additional professional development about EC and this will also be the case if UPA is rescheduled.

Ulipristal Acetate 30 mgs [redacted]

UPA has been available in Europe and other countries since 2009 and its introduction in Australia as an additional EC option for Australian women (TGA 2015) is welcomed. It is currently available without prescription in 25 European countries. This scheduling attests to the safety profile of UPA. In 23 of those countries, a pharmacist consultation is required as would also be the case if UPA becomes a Schedule 3 medication in Australia. In the other 3 countries (Norway, Sweden and Luxembourg) it is actually available on the open shelves in pharmacies. A recent publication by the World Health Organisation and the USA Centers for Disease Controls (Jatlaoui et al 2016) using direct and indirect evidence concluded that there are no special safety concerns for the use of UPA (and other ECPs) among women with particular medical conditions or personal characteristics, such as pregnancy, lactation or frequent ECP use. The literature supports the safety, efficacy and tolerance profile of UPA (Trussell et al 2016; Brache et al 2013; Fine et al 2010; Glasier et al 2010; Creinin et al 2006).

Additionally, UPA is more effective than LNG and is effective for up to 120 hours after unprotected sexual intercourse providing more leeway than LNG EC which is licensed for up to 72 hours. As with LNG EC, UPA should be taken as soon as possible following unprotected sexual intercourse and is more effective if taken in the first 24 hours (PI 2015). Many women are unaware that they are at the most fertile time of their menstrual cycle (Lundsbert et al 2014), so early use of EC will improve the chance of preventing or disrupting ovulation and thus a possibility for pregnancy. Removing the need for a doctor's prescription will facilitate this early use.

Conclusion

As is already the case for LNG EC, the barrier of obtaining a doctor's prescription for UPA should be removed. This will improve access and ensure that it can be obtained as soon as possible. As described previously in this submission, UPA is a safe and effective EC and is already available as a pharmacy only medication in 25 countries. [redacted] strongly supports the rescheduling of UPA to Schedule 3 as one of the strategies to assist women in controlling their fertility and reducing the number of unintended pregnancies as well as abortions in Australia and provide a bridge to ongoing and more effective contraception.

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[redacted]

6 May 2016

Medicines Scheduling Secretariat
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Proposal: Reschedule ulipristal to Schedule 3 Pharmacist Only Medicine to allow for emergency post-coital contraceptive use.

Chairperson, Medicines Scheduling Secretariat

[redacted]

[redacted] the opportunity to comment on the proposal to reschedule ulipristal from a [redacted] to Schedule 3 Pharmacist Only Medicine.

The enjoyment of the highest possible standard of physical and mental health is a human right. The Special Rapporteur on this righ[redacted]ains that:

> Realisation of the right to health requires the removal of barriers that interfere with individual decision-making on health-related issues and with access to health services, education and information, in particular on health conditions that only affect women and girls (United Nations, 2011).

[redacted]

[redacted]

Emergency contraception is an important component of the suite of contraceptive measures available to Australian women to reduce unintended pregnancy and maintain choice and control in their reproductive health. Any improvements to the efficacy of emergency contraception are welcomed by [redacted] as a step toward empowering ACT women to maintain good health and wellbeing.

However, with its current Schedule 4 status, many women in the ACT may miss out on the increased protection offered by ulipristal.

There are several barriers to accessing timely GP care in the ACT, which include:

[redacted]

- [redacted] territory in Australia (53.7 percent compared to an Australian average of 83 percent) (The Department of Health, 2015).
- [redacted] n [redacted] The Department of Health, 2015).
- [redacted] ed by [redacted] arative wealth of those around them and the relatively high cost of goods [redacted] ACTCOSS [redacted] t ACT women forgo primary health care when they cannot afford it.

[redacted]

- [redacted] lowest rates of GP availability in Australia, characterised by long waiting times and increased difficulty in booking consultations (Productivity Commission, 2016).
- Through community consultation [redacted] has heard that women can struggle to find GPs with appointments available on the day that they need them. This is even more difficult on weekends and public holidays.

Accessibility and appropriateness:

- Canberra is a city dependent on the car. This creates difficulties for women who rely on public transport or others to ferry them to appointments, particularly on weekends

[redacted]

[redacted]

and public holidays where available appointments may be further away and public transport more intermittent.

- For some groups of women, particularly those who have experienced trauma, the ability to choose a provid[redacted]imary health care is critical and may not be able to be controlled at short notice.

These barriers are compounded for women vulnerable to experiencing disadvantage, social isolation and marginalisation. This can include, for example: women experiencing domestic or sexual violence; women experiencing homelessness or housing insecurity; women on low or no income; young women; women with disabilities; and immigrant or refugee women.

[redacted]urs after intercourse. The barriers listed above mean that many women in the ACT may have delayed access to ulipristal or will simply utilise levonorgestrel instead. This means [redacted]

Only M[redacted]

Yours s[redacted]

[redacted]

[redacted]

Proposed amendments to the Poisons Standard, July 2016 (Medicines): Proposed amendments to the Poisons Standard, July 2016 (Medicines)

To amend the existing Schedule 4 entry and create a new Schedule 3 entry to allow for Ulipristal Acetate for emergency post-coital contraceptive use.

[redacted]

UPA EC has superior clinical efficacy compared to the currently available single dose levonorgestrel (LNG)

UPA EC is close to 3 times more effective than the currently available LNG when used within the first 24 hours after unprotected intercourse. (1) It remains effective when taken up to 120 hours post intercourse compared to LNG EC, which appears to have little if any efficacy after 96 hours. (2)

UPA is safe

A recent analysis of available data indicated no special safety concerns for women who conceived and continued a pregnancy after UPA EC use. (3, 4) The same study showed no concern in relation to women who used UPA repeatedly. While UPA has a limited number of precautions including, breastfeeding and severe liver disease this is no different to a number of other S3 medications.

Providing EC without prescription increases access

An analysis of German pharmacies showed a 64% increase in dispensing of UPA EC in 6 months after it become available without prescription, compared to the same months in the previous year when a doctor's prescription was required. (5)

Increasing access to UPA EC has the potential to reduce unintended pregnancies and abortion

Australia has a relatively high abortion rate. Interventions to prevent unintended pregnancy are needed. Widespread access to LNG EC has not been shown to have an effect on abortion rates.(6) Easier access to a more effective product has the potential to reduce unintended pregnancy and abortion.

Easier access to EC has not been shown to increase risky sexual behaviour

[redacted]

[redacted]

A number of studies have shown ready access to EC increases uptake without a corresponding increase in sexual risk taking or choices of less effective contraception. (7-11) Easier access equates to women being more likely to take EC.

Studies have shown pharmacy access to EC is effective

A pilot study has shown women increase their chances of taking up effective contraception after EC after a simple pharmacy intervention. (12) An analysis of international data concluded there is good evidence that community pharmacy emergency contraception services provide timely access to treatment and are highly rated by women.(13)

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UPA is cost effective

While the cost of UPA is likely to be higher than LNG EC, economic evaluations have shown it to be cost effective. (14)

Successful international non-prescription use

In November 2014 the European Medicines Agency approved UPA for emergency contraception as a non-prescription item. (15) The option has been taken up by at least 25 countries with a few having the product available without pharmacist's intervention.

Summary

In summary, [redacted] supports the proposal to amend the existing Schedule 4 entry and create a new Schedule 3 entry to allow UPA for emergency post-coital contraceptive use. Timely access to EC contributes to uptake. UPA EC has superior efficacy to LNG. It is safe and effective and many countries have successfully imitated without prescription pharmacy sales.

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