Public Consultation on the Proposed Amendments to the Poisons Standard

Notice under subsections 42ZCZL of the Therapeutic Goods Regulations 1990 (the Regulations)

The delegate of the Secretary to the Department of Health publishes herein all valid public submissions made in response to the invitation for public submission on the proposed amendments to the Poisons Standard. These submissions were considered by the July 2016 meeting of the Advisory Committee on Medicines Scheduling (ACMS).

In accordance with the requirements of subsection 42ZCZL of the Regulations these submissions have had confidential information removed.

Material claimed to be commercial-in-confidence was considered against the guidelines for the use and release of confidential information set out in Chapter 6 of the Scheduling Policy Framework for Medicines and Chemicals (SPF, 2015), issued by the Australian Health Ministers' Advisory Council. The SPF is accessible at https://www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals.

[redacted]

Submission to the Therapeutic Goods Administration, April 2016

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

[redacted]

[redacted]

[redacted]

[redacted]

Submission statement

It is estimated that almost half of all pregnancies in Australia are unplanned[i]. Unplanned pregnancy can occur for many reasons and under various circumstances. The reality is that contraception can fail, couples get carried away and some women may not be in a position to negotiate contraceptive use, due to the effects of alcohol or other drugs, lack of power in relationship decision-making, or being forced or coerced into having sex. For these women and couples emergency contraception is a viable option to prevent an unplanned pregnancy post unprotected sex.

[redacted] is supportive of measures to increase women's access to more effective contraception methods, including ulipristal, to reduce the number of unplanned pregnancies in Australia.

Clinical and biological evidence demonstrates that ulipristal is more effective than levonorgestrel, especially when taken within the first 24 hours after UPSI, at the time when the vast majority of women ask for EC. In addition, it is effective within 5 days (120 hours) of UPSI compared to 3 days (72 hours) for levonorgestrel. [ii]

Many barriers exist to contraceptive access for some women in Australia, and addressing these barriers is essential if women are to have full control over their fertility. As ulipristal is most effective if taken within 24 hours of unprotected sex, the removal of the requirement to obtain a prescription for ulipristal is imperative for more women to benefit from this more effective emergency contraceptive method.

The requirement of a doctor prescription is not necessary as is evidenced in many European countries and only places an additional barrier to women's access. In addition the Australian experience with levonorgestrel demonstrates the advantages for women of over the counter pharmacy access to emergency contraception.

[redacted] very supportive of the re-scheduling of ulipristal acetate for emergency contraception to become a pharmacy medicine (Schedule 3) by the TGA.

We are pleased the Therapeutic Goods Administration is considering this change to the scheduling of ulipristal to reduce the significant barrier of requiring a prescription and appreciate the opportunity to make this submission.

[i] D Mazza, C Harrison, A Taft, B Brijnath, H Britt, M Hobbs, K Stewart, S Hussainy 'Current contraceptive management in Australian general practice: an analysis of BEACH data' Medical Journal of Australia 2012; 197 (2): 110-114. Available online at https://www.mja.com.au/journal/2012/197/2/current-contraceptive-management-australian-general-practice-analysis-beach-data.

[ii] Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis *Anna F Glasier, Sharon T Cameron, Paul M Fine, Susan J S Logan, William Casale, Jennifer Van Horn, Laszlo Sogor, Diana L Blithe, Bruno Scherrer, Henri Mathe, Amelie Jaspart, Andre Ulmann, Erin Gainer*

[redacted]

[redacted]

ULIPRISTAL

I support the proposed amendment to the Poisons Standard July 2016 to amend the existing Schedule 4 entry and create a new Schedule 3 entry to allow for use of Ulipristal for Emergency Contraception.

Ulipristal has now been widely studied and research findings reported in the literature. Ulipristal is superior to all forms of Emergency Contraception (EC) presently available to women of reproductive age in Australia. It has higher efficacy than the levonorgestrel currently available over-the-counter to Australian women, but similar safety levels. It can be used up to 120 hours following unprotected sex.

Currently around 50% pregnancies in Australia are unplanned, according to several published studies, and half of these end in termination of the pregnancy. It is highly desirable that these rates be reduced. Being able to access EC in pharmacies OTC makes access to women concerned about contraceptive failure or unprotected sex very much easier than requiring a doctor's visit to obtain a prescription. I therefore support making Ulipristal available OTC as is levonorgestrel, with appropriate written information provided by the pharmacist to women seeking to purchase it.

My concern is solely for Australian women of reproductive age, who I believe will benefit from this change. It will have no impact on [redacted]

[redacted]

[redacted]

[redacted]

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

April 29th, 2016

To whom it may concern,

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

History of emergency contraception in Australia

Prior to 2002, there was no dedicated emergency contraceptive pill (ECP) product in Australia and women needed to obtain a doctor's prescription for off-label use of [redacted] (an oral contraceptive pill brand) as the Yuzpe method of EC (Calabretto 2012). The need for a doctor's prescription was often a barrier to obtaining EC and made it difficult to obtain it within the timeframe of 72 hours for that method of EC (Calabretto 2005). In 2001 the Australian Drug Evaluation Committee of the Therapeutic Goods Administration (TGA) approved [redacted] as the first proprietary brand of levonorgestrel (LNG) EC registered for use in Australia. It became available by doctor's prescription from July 2002 and was rescheduled by the TGA as a Schedule 3 medication in January 2004. Other LNG brands have subsequently been available in Australia as Schedule 3. It is also available in FPAA organisations and in some clinics and hospitals.

Access to emergency contraception

Since the availability of LNG as a Schedule 3 ECP product 12 years ago, potential users know that they can access EC from pharmacies with a pharmacist consultation without the need to obtain a doctor's prescription. This scheduling has significantly improved access to the ECP in Australia. 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. If UPA is rescheduled, timely access to this EC can also occur. An argument that was prominent at

the time of rescheduling of LNG EC to Schedule 3, concerned the potential loss of opportunities for GPs to provide information to their patients about more effective, longer-term contraceptive methods when they present for EC in pharmacies. However, it is important to note, that as a requirement for a pharmacist consultation in dispensing Schedule 3 medications, the pharmacist provides an assessment of the need for EC, comprehensive information about the medication and when appropriate, referral to other services. As primary health care professionals, pharmacists have demonstrated their ability to dispense LNG EC, and are in an excellent position to encourage users of ECPs to initiate or continue a more effective ongoing method. Additionally, pharmacists work within the guidelines provided by their professional body, the Pharmaceutical Society of Australia (PSA 2015) and undertake additional professional development about EC. This will also be the case if UPA is rescheduled and will include all aspects of the PI (2015), understanding when referral is needed and other practice considerations.

The need for women to obtain UPA EC following a consultation with a doctor 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 that may impact on this (Calabretto 2005). They may also 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.

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 most of the 25 countries, a pharmacist consultation is required as would also be the case if UPA was a Schedule 3 medication in Australia. In three of the 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 also supports its' efficacy and tolerance (Trussell et al 2016; Brache et al 2013; Fine et al 2010; Glasier et al 2010; Creinin et al 2006).

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 UPA is more effective if taken in the first 24 hours (PI 2015). Given that many women are also often unaware that they are at the most fertile time of their menstrual cycle (Lundsbert et al 2014), 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.

Conclusion

The timely and easily accessible provision of all types of ECPs to prevent an unwanted pregnancy requires removal of as many barriers as possible. Rescheduling of UPA from Schedule 4 to Schedule 3 in Australia is an important strategy to assist women in this situation. 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 this medication to reduce the number of unintended pregnancies and abortions in Australia.

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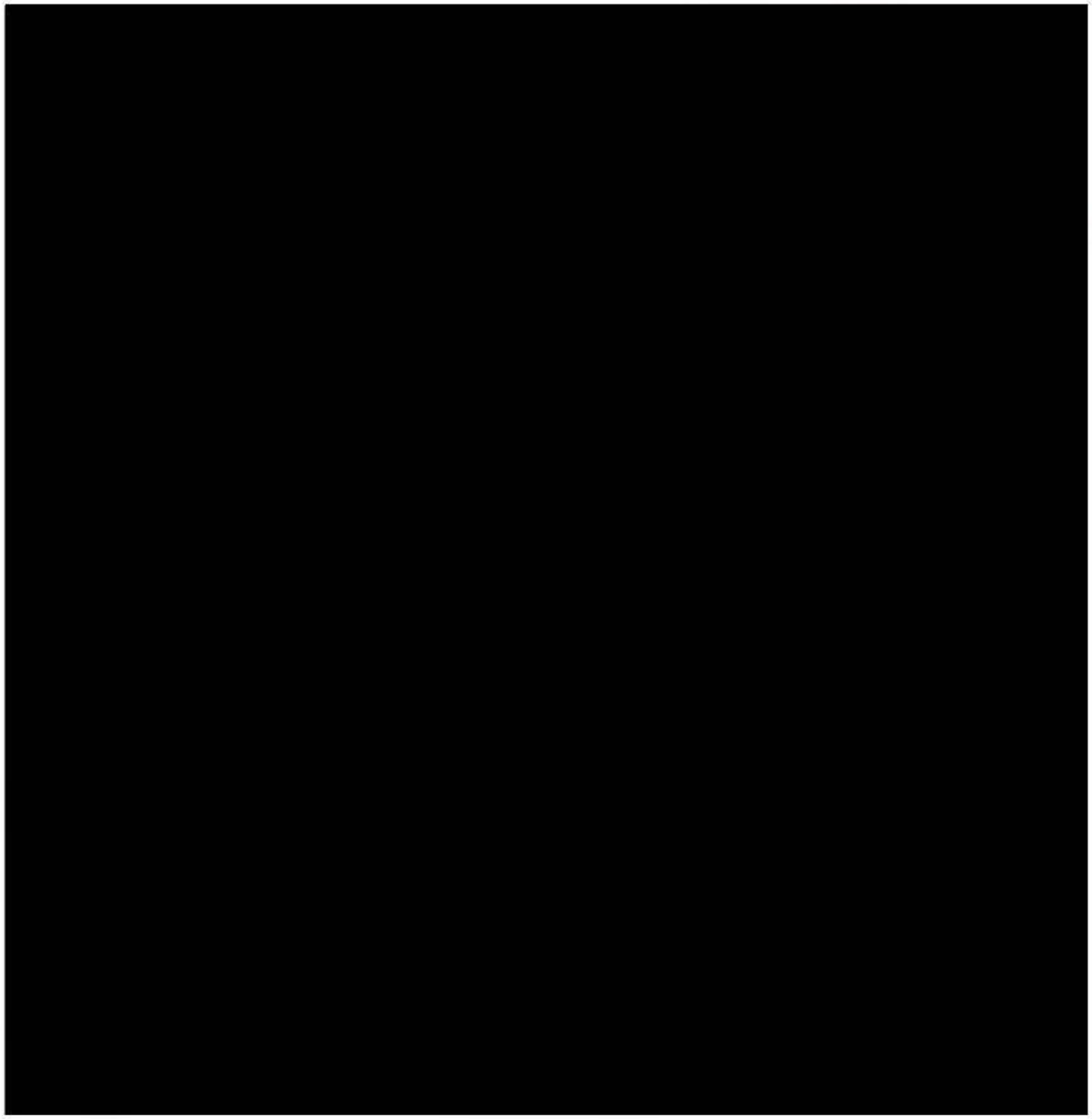

Medical Scheduling Secretariat
Medicines Scheduling
Therapeutic Goods Administration
Department of Heath
PO Box 100
Woden, ACT, 2606

Introduction

[redacted]

We welcome the opportunity to make a submission supporting the re-scheduling of UPA [redacted] from a Schedule 4 prescribed medication to a Schedule 3 drug.

Background

Ulipristal acetate (UPA) 30mgs was first listed on the Australian Register of Therapeutic Goods as an emergency contraceptive (EC) in Australia in March 2015 under the tradename [redacted] It is a relatively new emergency contraceptive pill option for women but has been available in Europe and other countries since 2009.

UPA is currently available by private prescription for use after unprotected intercourse, contraceptive failure or sexual assault. It is a selective progesterone receptor modulator which works as an emergency contraceptive by preventing or delaying ovulation until five days after intercourse when sperm are no longer viable in the female genital tract.

Ulipritsal Acetate 30mgs [redacted]

[redacted] supports the rescheduling of UPA [redacted] from a Schedule 4 prescribed medication to a Schedule 3 drug which would be available at pharmacies without a prescription given the demonstrated safety profile of UPA and as this would further promote timely and easy access to emergency contraception in Australia thereby supporting better public health outcomes.

Prevention of unintended pregnancy is a significant public health issue affecting women of all reproductive ages, including teenagers. Unintended pregnancy can result from failed contraception such as condom breakage or missed contraceptive pills as well as non-use of contraception. UPA taken soon after unprotected intercourse is proven to prevent unintended pregnancy.

Experience of UPA is extensive across the globe. UPA was first approved for emergency contraception in Europe in 2009 and is now available across 89 countries worldwide. UPA has been made available as a non-prescription medication in 25 countries including the UK and, most recently, Switzerland.

The 1.5mg levonorgestrel emergency contraceptive pill (LNG-ECP) has been included in Schedule 3 since 2004 with no evidence of harm at a community or individual level. UPA has a similar safety profile but superior effectiveness to LNG-ECP.

A meta-analysis[1] of itwo non-inferiority trials has shown that UPA is significantly more effective than LNG-ECP at preventing pregnancies if taken within 24, 72 and 120 hours of unprotected intercourse. UPA is licensed for use up to 120 hours after unprotected intercourse with proven effectiveness on the 4th and 5th day while LNG-ECP is only licensed for 72 hours with a loss of effectiveness on day 5. Administration of UPA within the first 24 hours is associated with greater effectiveness which makes timely access essential.

The safety of UPA is well established and it has few contraindications or precautions. There is no evidence to suggest that UPA taken inadvertently during pregnancy results in harm to either the pregnancy or the foetus.

Making UPA available through pharmacy settings without the need to see a doctor allows women more autonomy over their reproductive health outcomes. Experience of the sale of the LNG-ECP through pharmacies over the last decade has not raised any issues of concern at either a community or individual level. Provision of emergency contraception without a prescription is not associated with an increase in sexual risk taking including increased frequency of unprotected intercourse, increased sexually transmitted infections or reduced use of effective ongoing methods of contraception.

Community pharmacists are experienced in the provision of the existing LNG-ECP product and the provision of UPA will involve an extension of this service. Pharmacists can be supported by the provision of information and training as well as evidence-based checklists so that they can fulfil their professional duty to provide professional advice to women. This will ensure that UPA is used safely and effectively and that women are provided with information about effective methods of ongoing contraception.

Conclusion

[redacted] supports timely and easily accessible provision of all types of ECP to prevent unwanted pregnancy, including UPA, and supports pharmacy access for UPA [redacted] without the need for a doctor's prescription. Removing this additional barrier to timely access for this effective and safe method of emergency contraception has already occurred in many countries and the public health benefits will only be realised if UPA is made available to women through their local pharmacy.

For further information, please contact:

[redacted]

Yours sincerely,

[redacted]

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[1] Glasier AF, Cameron ST, Fine PM, Logan SJ, Casale W, Van Horn J, Sogor L, Blithe DL, Scherrer B, Mathe H, Jaspart A, Ulmann A, Gainer E, 2010 Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferioity trial and meta-analysis, Lancet 375:555-62

[redacted]

Medicines Scheduling Secretariat,
Medicines Scheduling,
Therapeutic Goods Administration,
Department of Health,
PO Box 100,
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Australia.

April 26th 2016

Dear Sir/Madam,

Re: [redacted] rescheduling of ulipristal acetate for emergency contraception application (EllaOne).

[redacted] would like to support the [redacted] application the rescheduling of ulipristal acetate - [redacted] has a scheduled 3 drug for emergency contraception. [redacted] believe rescheduling this drug to a pharmacy medicine will provide more choice/alternative options to women who require emergency contraception. Prior to the early 2000's, women had little choice in Australia when discussing the emergency contraception pill (previously known has morning after pill) and were required to visit a Doctor to obtain a script.

Moving forward, Levonorgestrel-based hormonal emergency contraception is already available across the counter and [redacted] would provide another choice of product. This product has been available overseas to women for the past seven years and it is time for Australian women to have the same choice when discussing unplanned pregnancies and abortions.

Unfortunately, even in Australia not all States/Territories offer the same choice for all women for example in the Northern Territory women are not able to access RU486 and surgical abortions are limited and often with a six week waiting period. Women who can afford the cost fly Interstate to access support and abortions.

We need to support women with safe choices and [redacted] supports unequivocally the rescheduling of ulipristal acetate – [redacted]

Yours Sincerely,

[redacted]

[redacted]

[redacted]

submission on scheduling of ulipristal acetate

[redacted]

Contents

[redacted]

Introduction

[redacted]

Preamble

[redacted] welcomes the opportunity to provide input to the scheduling of *ulipristal acetate for emergency contraception* as part of the Consultation: Proposed amendments to the Poisons Standard, July 2016 (Medicines). The reduction of social and health inequities should be an over-arching goal of national policy and recognised as a key measure of our progress as a society. The Australian Government, in collaboration with the States/Territories, should outline a comprehensive national cross-government framework on reducing health inequities. All public health activities and related government policy should be directed towards reducing social and health inequity nationally and, where possible, internationally.

Health Equity

[redacted]

- Health inequity differs from health inequality. A health inequality arises when two or more groups are [redacted] and found to differ. Whether this inequality (disparity) is [redacted] ces between (or among, or within) groups.[1]
- [redacted] result of unfair, unjust social treatment – by governments, organisations [redacted] ing in macro politico-economic structures and policies that create living and working [redacted]

[redacted] priate reproductive health services, including contraception, is essential for every Australian woman's health and wellbeing. While contraception should be the [redacted] inequity can create inequitable relationships between [redacted] omen bear the primary burden of reproductive health, including the [redacted] th

Social Determinants of Health

[redacted] including the health system. These circumstances are shaped by the distribution of money, power and resources at global, national and local levels, which are themselves influenced by policy choices. The social determinants of health are mostly responsible for health inequities – the unfair and avoidable differences in health status seen within and between countries[5]. **This is particularly pertinent when considering issues such as access to emergency contraception.**

The determinants of health inequities are largely outside the health system and relate to the inequitable distribution of social, economic and cultural resources and opportunities. Health inequities are the result of

the interaction of a range of factors including: macro politico-economic structures and policy; living and working conditions; cultural, social and community influences; and individual lifestyle factors.

[redacted] Response to the ulipristal acetate for emergency contraception as part of the Consultation: Proposed amendments to the Poisons Standard, July 2016 (Medicines).

Background

[redacted]

The reclassification of ulipristal as a schedule three medicine would be consistent with the classification of the current available emergency contraception levonorgestrel, which has been available as a schedule [redacted] medicine for the past eleven years[7]. This experience also demonstrates the ability for appropriate and safe emergency contraception management from pharmacies and provides a framework for how ulipristal [redacted].

Provision of safe and accessible emergency contraception is an essential health service

[redacted] ntraception is poorly understood within Australia[8]. [redacted] strongly advocates for access to safe and accessible emergency contraception as an essential health service. Ulipristal is currently [redacted] on[9] which provides greater opportunity for [redacted] cing the impact of unintended pregnancies on individuals and the [redacted]. Studies have also suggested that the use of emergency contraception can be a [redacted] eased or more consistent used of standard contraception[11].

All forms of contraception (including emergency contraception) should be affordable and accessible

[redacted] found accessing emergency contraception had no indirect risks or danger compared to prescription[13].

Ulipristal acetate provides increased efficacy and longer window of opportunity to prevent unintended pregnancy compared to other available emergency contraception

There is an extensive amount of evidence which evaluates the safety, efficacy and efficiency (in relation to a longer window of emergency contraception availability) of ulipristal internationally and within Australia[14]. Given ulipristal is appropriate to be used five days following UPSI there is a significant benefit to women's health, and broader public health outcomes, in reclassifying this to a schedule three medicine. Ulipristal has

been found to be more effective in preventing pregnancy in the first 24 hours then the currently available emergency contraception however given the need to gain a prescription for ulipristal it is unlikely that many women will be able to access this in this time frame. [redacted] strongly advocates for health equity. However the current schedule four classification of ulipristal will impact some women disproportionately more than others, for example those in rural areas, women from low socioeconomic backgrounds and women new to Australia are more likely to be unable or be hesitant access a general practitioner (due to financial reasons, lack of access to health services and/or waiting times).

Conclusion

[redacted] supports the reclassification of ulipristal as a schedule three medicine. We are particularly keen that the following points are highlighted:

[redacted]

5 May 2016

[redacted]

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[redacted]

[redacted]

Therapeutic Goods Administration Consultation: Proposed amendments to the Poisons Standard, July 2016 (Medicines)

[redacted]

Unintended pregnancies are a significant public health issue that exert an enormous burden on public funds, as well as potentially adversely affecting women's health and their social and financial wellbeing. Australia has relatively high rates of unintended pregnancy compared to countries in northern Europe. Emergency contraception (EC) allows women to prevent unwanted pregnancies in situations of contraceptive failure or non-use. Currently there are two methods of oral EC available in Australia. Levonorgestrel emergency contraception is marketed under the brand names [redacted] It is an S3 medication (pharmacist only medication). Ulipristal acetate [redacted] is currently an S4 medication but [redacted] supports its listing as an S3 medication.

Ulipristal acetate, an orally active selective progesterone receptor modulator, is the most effective of the oral EC methods available with demonstrated efficacy up to 120 hours after unprotected sexual intercourse or contraceptive failure. It is licensed for EC in 89 countries and has been administered to more than five million women worldwide. Compared to the oral EC levonorgestrel, ulipristal is more effective at preventing pregnancy. In a meta-analysis of two studies comparing ulipristal to levonorgestrel oral EC, the odds of pregnancy among ulipristal users was found to be 42% lower than among users of levonorgestrel in the first 72 hours after sexual intercourse and 65% lower in the first 24 hours. Further, while levonorgestrel is effective up to 72 hours after unprotected sexual intercourse or contraceptive failure, ulipristal remains effective for up to 120 hours in such situations.

[redacted] supports the change of ulipristal acetate from a Schedule 4 entry to a Schedule 3 entry to allow for emergency post-coital contraceptive use. As outlined above, ulipristal is both more effective and has a longer window of efficacy than levonorgestrel. Additionally, the safety profile of ulipristal is good and the adverse effects commonly associated with its use are mainly mild or moderate, short-lasting, self-limiting, and similar to levonorgestrel. Making ulipristal available through an S3 schedule would increase access to this more effective, post-coital medication and potentially contribute to reducing unintended pregnancies.

6 May 2016