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**Submission to National Drugs and Poisons Scheduling Committee  
June 2003 Meeting**

Regarding agenda item 6.6 Levonorgestrel – consideration of a proposal to reschedule from Schedule 4 to Schedule 3 when in a two tablet pack, of 0.75mg per tablet, for emergency post-coital contraception

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This submission will address the following subsections of section 52E of the Therapeutic Goods Act 1989:

- (b) the risks and benefits associated with use of a substance
- (d) the extent and patterns of use of a substance
- (f) the need for access to a substance, taking into account its toxicity compared with other substances available for a similar purpose
- (g) the potential for abuse of a substance
- (h) the purpose for which a substance is to be used
- (i) other matters necessary

In regards to each of the above points, particular attention will be paid to the issue of rescheduling Levonorgestrel in a two-tablet pack (0.75mg per dose) from Schedule 4 to Schedule 3 for emergency post-coital contraception.

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## 1. The Australian Reproductive Health Alliance

The Australian Reproductive Health Alliance (ARHA) is a non-government, not-for-profit agency that was established as a direct result of the Cairo Program of Action (PoA) which was agreed upon at the UN International Conference on Population and Development (ICPD) in 1994. While ARHA's principal focus is ensuring Australia meets its PoA commitments in the area of overseas development assistance, we also maintain the objective of advocating domestic policy that is consistent with PoA objectives. Ensuring Australian men and women have access to choice in areas affecting their sexual and reproductive health is a key objective of ARHA.

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### 2.1 The Risks and Benefits Associated with the use of Levonorgestrel

A study commissioned by the World Health Organisation, published in the Lancet in 1998, deemed Levonorgestrel\* only medication to be the 'gold standard' in hormonal emergency post-coital contraception<sup>1</sup>. The method of administering one pill containing .75mg of Levonorgestrel as soon as possible, within 72 hours after unprotected intercourse, followed by a second dose 12 hours later has been shown to be effective in preventing unwanted pregnancy in approximately 85% of cases<sup>2</sup>. This finding was supported by a Cochrane review conducted in 2002<sup>3</sup>. The same Cochrane review also concluded that effective forms of emergency contraception (EC) should be made available to all women upon request.

EC is the most effective means of preventing unwanted pregnancy following unprotected intercourse. The major benefits therefore in ensuring EC is available to women include a reduction in unplanned pregnancies and abortion. Recent Australian studies show that pregnancy termination is one of the most common procedures performed each year with approximately eighty thousand abortions taking place annually in Australia<sup>4</sup>. A 2002 study suggests that availability of EC plays a key role in reducing the rate of abortion<sup>5</sup>.

The major benefits to rescheduling Levonorgestrel to schedule 3 (restricted to supply by pharmacists) are:

- ◆ EC provides a narrow window of opportunity (up to 72 hours after unprotected intercourse) for women to avoid unwanted pregnancy without having to resort to abortion. The shorter this timeframe is, the greater the likelihood that EC will be effective<sup>6</sup>. For this reason ensuring that access to EC is simple and as broad as possible, with due consideration to the strength of the pharmaceutical, is paramount.
- ◆ The process of scheduling an appointment with a GP and visiting a pharmacist to fill the prescription creates a time delay which may interrupt the effectiveness of the Levonorgestrel. Access to EC without the need for an appointment, has the potential to increase effectiveness of EC through allowing for the earliest possible administration.
- ◆ Pharmacies are conveniently located and many are open on evenings, weekends and holidays (when people may be most likely to engage in unprotected intercourse). As such,

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\* Throughout this submission references to Levonorgestrel are intended to refer specifically to Levonorgestrel in a two-tablet packet of 0.75mg per packet designed for use as emergency post coital contraception

non-prescription supply of EC through pharmacies is a logical means for dispensation given that provision of a two-tablet pack of Levonorgestrel does not pose a risk of overdose, nor potential for addiction. Additionally, the two-step regime is easy to follow and all women receive the same dosage. If the method of usage is made clear to the consumer by the pharmacist at point of sale, and on the product label, it is unlikely that women will misunderstand or misuse Levonorgestrel<sup>7</sup>.

- ♦ The large number of pharmacies in most metropolitan, and some regional, areas increases the points at which women can access EC if it is available non-prescription. This reduces the likelihood that women will be unable to access EC due to doctors or pharmacists refusal to dispense the medication due to their personal religious or moral beliefs.

Reasons cited by young women for not accessing EC include cost, embarrassment, lack of transport and inability to explain absence from school while visiting a doctor<sup>8</sup>. The purpose of making medications such as Levonorgestrel easily accessible is to ensure women avoid unwanted pregnancy and/or having to undergo an abortion. This point is particularly salient for young women where unwanted pregnancy is likely to affect factors such as their education and future employment opportunities. Non-prescription supply of EC will go some way to reducing the above-cited factors which inhibit young women's access to EC in the following ways:

- ♦ The cost of GP services is becoming increasingly restrictive for people on low incomes. Young people often lack any income and paying for the cost of a GP consultation may simply be beyond their means. Unless young people have ready access to free medical services, such as Family Planning Clinics (which they are unlikely to find in many regional areas), obtaining a prescription for EC within 72 hours may be difficult or impossible. Reducing costs associated with obtaining EC may 'tip-the-balance' in favour of EC for a young woman who is weighing up the risk of pregnancy against the cost of a GP consultation.
- ♦ Provision of Levonorgestrel through a pharmacy may not reduce entirely the embarrassment associated with requesting EC. However, it allows it to be a one-step process, so obtaining EC is not a matter of having to confront a number of people regarding the situation. Additionally, there are likely to be a number of pharmacies from which EC can be purchased. Consumers may therefore have greater choice as to the locality in which they obtain EC and the pharmacist they chose to approach. For women who feel more comfortable requesting EC through a GP, that option will still be available.

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## **2.2 The Extent and Patterns of Use of Levonorgestrel**

A trial conducted in the UK, throughout the Manchester and Salford urban areas, in which EC was supplied through pharmacies free-of-charge indicated a high level of demand for the medication. Between December 1999 and March 2001 there were over thirteen thousand consumers presenting with requests for EC. The most commonly cited reasons for seeking EC were a burst condom (46%) and unprotected sex (43%). The age range for women requesting EC spanned from 13-56 with most requests coming from women aged in the 20-29 age bracket. Only

4% of requests were from women aged under 16 years<sup>9</sup>. These results suggest EC is likely to be used as an emergency back-up when other methods of contraception fail or are not used.

Australian studies indicate that EC is currently under-utilised in Australia due to lack of awareness about, and accessibility of, the medication<sup>10</sup>.

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### **2.3 The Need for Access to Levonorgestrel**

Please refer to section 2.1

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### **2.4 The Potential for Abuse of Levonorgestrel**

One of the arguments against the supply of Levonorgestrel is the belief that it is an abortifacient. However, Levonorgestrel acts by inhibiting implantation of the ova. Fertilization of the ova is a necessary step toward pregnancy, but pregnancy does not commence unless or until implantation occurs<sup>11</sup>. This generally takes place around one week after ovulation. Levonorgestrel does not work post-implantation and therefore would be ineffective as an abortifacient<sup>12</sup>. Concerns that Levonorgestrel could be used to administer abortion (whether legal or illegal) are unwarranted.

Similarly, there is no evidence that Levonorgestrel will damage an unborn foetus if a woman uses it while already pregnant, even in the early stages. Pregnancy is a cited contraindication for Levonorgestrel, however this refers to the lack of efficacy of the medication rather than risk to mother or foetus<sup>13</sup>.

Intentional or unintentional overdose of Levonorgestrel has been shown to not cause serious harm. Likely side effects may include nausea, vomiting, or menstrual irregularity<sup>14</sup>. There are a number of other medications currently available non-prescription, including aspirin and paracetamol, which can potentially cause much greater harm through misuse.

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### **2.5 The Purpose for Which Levonorgestrel is to be used**

Given the points made above in section 2.4, it is unlikely that Levonorgestrel will, or can, be used for purposes other than emergency post-coital contraception. It will be used by women who have engaged in unprotected intercourse, or suspect their contraception may have failed, and do not wish to become pregnant.

EC does not supplant other forms of contraception. There is no evidence to suggest that access to EC leads women to favour it over use of the pill or barrier methods of contraception<sup>15</sup>. It is reasonable to assume Levonorgestrel, if made available non-prescription, will be used for emergency post-coital contraception only, not for a regular contraceptive method (please refer also to sections 2.4 and 2.6).

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## 2.6 Other Matters Regarding Levonorgestrel

Concerns often raised about non-prescription supply of Levonorgestrel through pharmacies are political not medical. The major points raised rest on two arguments, 1) that EC is akin to abortion, and 2) that the availability of EC encourages irresponsible and/or underage sex. As noted in point 2.4, Levonorgestrel can not be used as an abortifacient. As such, the argument that non-prescription dispensation of EC amounts to legalized, non-surgical abortion is without merit. In regards to the latter point, there is no evidence to indicate that availability of emergency post-coital contraception, or ordinary contraceptive methods such as the use of condoms, encourages sexual activity<sup>16</sup>. Further, there is evidence that women are unlikely to abandon ongoing use of regular contraception or condoms in favour of EC, even where it is readily available<sup>17</sup>.

The use of EC is a responsible and rational act taken by women seeking to avoid unwanted pregnancy. Accessibility of EC is in the interests of reproductive health given that it is considerably less invasive and risky than abortion. Unfortunately, rather than being seen as part of a range of possible options for contraception, EC has become stigmatized and associated with irresponsible sex. This is a political position that can be reversed through education.

Another argument sometimes cited against non-prescription sales of EC is that the consultation provides an excellent opportunity for physicians to provide women information on ongoing forms of contraception and to screen for sexually transmitted infections (STIs). If a woman requires EC following unprotected sex then she may also have been exposed to a range of common STIs or HIV<sup>18</sup>. However, the following points should be noted:

- ◆ Not all women seeking EC will be in need of STI screening. A woman may seek EC if she has forgotten to take her regular contraceptive pill, or if her usual dose has been interrupted for other reasons such as vomiting. In other words, EC may be required by women in monogamous relationships who have chosen to use the pill rather than other forms of contraception. In this case an STI test may not be necessary. The situation of women seeking EC should not be presumed, nor generalised.
- ◆ Women who are more likely to access EC through a pharmacist because they are unwilling to visit a physician may find the possibility of STI screening extremely intimidating. Hence, limiting access of EC to prescription-only for the reason of encouraging STI screening may present a further barrier to access for some women.
- ◆ Provision through a pharmacy allows women to access EC as quickly as possible. It is reasonable to assume that, if necessary, many women will seek STI and HIV screening following unprotected sex. If women are not seeking regular STI screening, the issue should be dealt with through health education and attention to appropriate service provision rather than limiting access to EC.

Over the past few decades significant advances have been made in encouraging people to take greater control of their preventative health care needs and treatment. The rationale behind this is that greater participation of the consumer in treatment decision making and maintenance leads to better health outcome because people are more likely to adhere to a treatment plan and take active charge of their ongoing health and wellbeing. This trend has been particularly strong in the area of women's health. Women have been encouraged to learn about their reproductive health needs, make contraceptive decisions which best suit their individual circumstances and undertake self care through measures such as breast self-examination. Non-prescription supply of EC is consistent with this trend in women's health care. It enables women to control, and take responsibility for, their reproductive health care needs<sup>19</sup>.

EC currently is available without prescription in over 27 countries, including the UK, New Zealand, Switzerland, South Africa and France. Trials of non-prescription access to EC have also been conducted in Washington State and British Columbia, Canada<sup>20</sup>.

In the UK, EC became available without prescription in 2001 for women 16 years or over. The French experience saw non-prescription EC available in June 1999. Additionally, since October 2000, EC has been available from nurses in French secondary schools<sup>21</sup>. There are no age restrictions on supply of EC and 65% of the cost is refundable through national health insurance<sup>22</sup>.

In rescheduling Levonorgestrel to schedule 3, Australia would simply be following precedents set by other Western countries.

Levonorgestrel provided in a two-tablet packet, 0.75 mg per packet, is a safe, effective post-coital prophylaxis. Maintaining a prescription only requirement on this product is not in the interests of women's reproductive health as it creates a time-delay that potentially impedes the efficacy of EC. Enhancing access to EC contributes to a reduction in unintended pregnancies and abortion.

EC supplements other forms of contraception, it does not replace them. As part of a range of contraceptive choices, EC offers women an opportunity to avoid unintended pregnancy in the event that other contraceptive methods fail or for various reasons have not been utilised. Women are capable of, and should be given every opportunity to, determine their own reproductive health choices. Where medications are safe for use on a non-prescription basis, as Levonorgestrel has been shown to be in several countries, there is no reason to maintain prescription only access.

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<sup>1</sup> Editorial 2003 *Emergency Contraception* BMJ v326, 12 April pp775-776

<sup>2</sup> von Hertzen, Helena, Piaggio, Gilda, Ding, Juhong, Chen, Junling et al 2002 *Low Dose Mifepristone and Two Regimes of Levonorgestrel for Emergency Contraception: A WHO Multicentre Randomised Trial* The Lancet, December 7 pp1083-1810

<sup>3</sup> Cheng, L, Gulmezoglu, A, Excurra, E, Van Look, P 2002 *Interventions for Emergency Contraception* Cochrane Database of Systematic Reviews 2002(1)

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- <sup>4</sup> National Health and Medical Research Council (NHMRC) 1996 *An Information Paper on Termination of Pregnancy in Australia* Commonwealth Department of Health and Family Services, Canberra Cited in The Public Health Association of Australia *Policy on Emergency Contraception* available at <http://phaa.net.au/policy/EC.htm>
- <sup>5</sup> Boonstra, Heather 2002 *Emergency Contraception: Steps Being Taken to Improve Access* The Guttmacher Report on Public Policy pp10-13
- <sup>6</sup> Piaggio, G, von Hertsen, H, Grimes, D, Van Look, P 1999 *Timing of Emergency Contraception with Levonorgestrel or the Yuzpe Regime* Lancet v353 p721
- <sup>7</sup> Raymond, EG, Dalebout, SM, Camp, SI 2002 *Comprehension of a Prototype Over-the-Counter Label for an Emergency Contraception Pill Product* Obstetrics and Gynecology v100, pp342-349 cited in Grimes, D 2002 *Switching Emergency Contraception to Over-the-Counter Status* New England Journal of Medicine v347 no. 11, pp846-849 Raymond et al (2002) demonstrated sound comprehension of labeling information provided on the label regarding dosage, efficacy and contraindications.
- <sup>8</sup> Editorial 2003 *Emergency Contraception* BMJ v326, 12 April pp775-776; Editorial 2001 *Emergency Contraception Still and Unknown Quantity* Flinders Journal April 30-May 13, interview with Helen Calabretto who is undertaking a PhD in the School of Nursing and Midwifery at Flinders University. Calabretto interviewed 42 young women about their knowledge, attitudes and experiences using EC.
- <sup>9</sup> Schenk, Katie 2001 *Emergency Contraception: The UK Experience* Reproductive Health Alliance, UK
- <sup>10</sup> The Public Health Association of Australia *Policy on Emergency Contraception* available at <http://phaa.net.au/policy/EC.htm>
- <sup>11</sup> Grimes, D 1997 *Emergency Contraception – Expanding Opportunities for Primary Prevention* New England Journal of Medicine v 337 no. 15, pp1077-1079
- <sup>12</sup> Royal Australian College of General Practice 2002 *Emergency Contraceptive Pill (ECP) Levonorgestrel 750 microgram: Managing Risks Associated with Unprotected Sexual Intercourse* RACGP, Canberra
- <sup>13</sup> Grimes, D 2002 *Switching Emergency Contraception to Over-the-Counter Status* New England Journal of Medicine v347 no. 11, pp846-849; Glasier, A, Baird, D 2003 *The Effects of Self-Administering Emergency Contraception* The New England Journal of Medicine v339 no. 1, pp1-4
- <sup>14</sup> *ibid*
- <sup>15</sup> Grimes, D 2002 *Switching Emergency Contraception to Over-the-Counter Status* New England Journal of Medicine v347 no. 11, pp846-849; Glasier, A, Baird, D 2003 *The Effects of Self-Administering Emergency Contraception* The New England Journal of Medicine v339 no. 1, pp1-4
- <sup>16</sup> Latham, Melanie 2001 *Deregulation or Emergency Contraception: A Way Forward for Women's Health Care?* Feminist Legal Studies v9, pp 221-246
- <sup>17</sup> Boonstra, Heather 2002 *Emergency Contraception: Steps Being Taken to Improve Access* The Guttmacher Report on Public Policy pp10-13; Glasier, A, Baird, D 2003 *The Effects of Self-Administering Emergency Contraception* The New England Journal of Medicine v339 no. 1, pp1-4
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- <sup>22</sup> Boonstra, Heather 2002 *Emergency Contraception: Steps Being Taken to Improve Access* The Guttmacher Report on Public Policy pp10-13