



Submission of Family Planning NSW

Inquiry into approval processes for new drugs and novel medical technologies in Australia

October 2020

House of Representatives Standing Committee on Health, Aged Care and Sport
Via online submission
By 13 October 2020

Family Planning NSW welcomes the opportunity to make a submission to the House of Representatives Standing Committee on Health, Aged Care and Sport on the *Inquiry into approval processes for new drugs and novel medical technologies in Australia*.

About Family Planning NSW

Family Planning NSW is the state's leading provider of reproductive and sexual health services. We are experts on contraception, pregnancy options, sexually transmissible infections (STIs), sexuality and sexual function, menstruation, menopause, common gynaecological and vaginal problems, cervical screening, breast awareness and men's and women's sexual health.

As an independent, not-for-profit organisation, we recognise that everybody in every family should have access to high-quality clinical services and information. Family Planning NSW provides clinical services to more than 30,000 clients annually. We have five fixed clinics in NSW and use innovative partnerships to deliver services in other key locations across the state.

We provide information and health promotion activities, and best practice education and training in reproductive sexual and health for doctors, nurses, teachers and other health, education and welfare professionals. Our services are targeted to marginalised and disadvantaged members of the community, including people from culturally and linguistically diverse and Aboriginal and Torres Strait Islander backgrounds, refugees, people with disability, young people and people from rural and remote communities.

Our work is evidence-based, and shaped by our research, published clinical practice handbooks on reproductive and sexual health, nationally recognised data and evaluation unit and validated through extensive clinical practice. Our mission is to enhance the reproductive and sexual health and rights of our communities by supporting all people to have control over and decide freely on all matters related to their reproductive and sexual health throughout their lives.

Unmet need for contraception in Australia

We note that the House of Representatives Standing Committee on Health, Aged Care and Sport will inquire into the approval processes for new drugs and novel medical technologies in Australia, with a particular focus on those for the treatment of conditions where there is high and unmet clinical need.

Reproductive and sexual health is an area where there is high unmet need, particularly in regard to equitable contraception access. However, Australia can streamline timely access to evidence-based new drugs and novel medical technologies available in comparable high income countries for people who could benefit from them.

Finding a contraceptive methods to suit an individual's needs can be difficult for some. Increasing access to the complete range of options available in other countries including New Zealand, the UK and Canada will support filling the gap in unmet need for contraception.

One in four Australian women have experienced an unintended pregnancy in the past decade. About half of these pregnancies occurred for women not using contraception, and about one third ended in abortion.(1)

In Australia, there is a 10.7% unmet need for family planning - when a woman wants to stop or delay childbearing but is not using contraception.(2) An unmet need for family planning has significant implications for individual women, their families and communities. Research shows that (3):

- firstborn children of mothers under the age of 18 are at the greatest risk of neonatal mortality, preterm birth, and infant mortality
- meeting women's need for contraception can have a large impact on maternal, infant and child deaths

- reducing fertility rates can improve infant survival, children’s health, education and wellbeing, women’s economic productivity and household income.

Highly effective long-acting reversible contraception (LARC), namely implants and intrauterine devices, is globally advocated by governments as a key strategy to reduce unintended pregnancy.(4) These contraception methods are more than 99% effective, compared with the oral contraceptive pill (93% effective with typical use) and the male (external) condom (88% effective with typical use). However, despite this evidence, use of LARC is low in Australia.(5, 6)

Summary of recommendations

Family Planning NSW makes the following recommendations:

1. increase investment in reproductive and sexual health research
2. increase women’s involvement in clinical trials, particularly young and adolescent women, to determine the safety, effectiveness, and tolerance of drugs for all consumers
3. improve access to the full range of contraceptive drugs and medical technologies in Australia
4. address lack of remuneration for nurses and adequacy of remuneration for doctors as a critical barrier to ensuring the availability of new drugs, devices and novel therapies for consumers
5. provide avenues to develop new contraceptive products and repurpose other products that can be used for contraception
6. prioritise investment in clinical trials for new contraceptive drugs and technologies
7. improve access to a wider range of contraceptives (that have proven effectiveness and are used internationally) in Australia via changes to regulatory processes.

Key points

1. The range of new drugs and emerging novel medical technologies in development in Australia and globally, including areas of innovation where there is an interface between drugs and novel therapies

Reproductive and sexual health

To address the unmet need for contraception in Australia, there is a need to increase the range of drugs and emerging novel medical technologies in development. There is great opportunity to explore the possibilities for personalised medicine and a need to further explore side-effects of existing and new contraceptives, for example, on mood changes.

Equity of women’s participation in clinical trials

Equitable representation of women in pharmaceutical research is imperative for determining the safety, effectiveness, and tolerance of drugs for all consumers. Historically, women have been excluded from participating in clinical research leading to a lack of knowledge regarding drug effects and their consequences.(7) Gender-based differences must be reflected as they may account for variations in drug outcomes: due to different physiological makeup, experiencing disorders at different rates to men, and gender not being considered in the analysis of drug trial outcomes.(7) Due to under-involvement of women in clinical trials, the provision of medicine for women is less evidence-based than for men.(8) In clinical trials involving contraceptives, young women under 18 years have historically been underrepresented due to ethical constraints.

An Australian study found Human Research Ethics Committees do not play an active role in monitoring the inclusion of men and women in Australian clinical research because they do not consider it to be a priority. The Committees do however identify apparent sex discrimination or unfair recruitment strategies and do not believe that research should be impeded on the grounds of sex inequity among the research participants.(9) Involvement of women can be increased through participation of more reproductive and sexual health clinics in clinical trials.

Contextual factors

Aside from the types of drugs that are on the Australian market, multiple factors contribute to contraceptive availability and use(10), including

- government policy on family planning
- the types of health care providers who are authorised and trained to provide contraceptives
- cost differences, and
- the geographical availability of services providing reproductive and sexual healthcare.

Structures to promote consumer access can increase the take-up of contraceptives. For example, the use of emergency contraception has increased since it was made available without a doctor's prescription in 2004.(11)

Another example of structural impacts on availability is the low uptake of IUDs. The low uptake is due to limitations regarding doctor and nurse remuneration and training opportunities and a lack of awareness or misperceptions by both consumers and providers.(4) Uptake could be improved by increasing the number of trained IUD inserters.(12) There is international and domestic evidence, including evidence of cost-effectiveness, that Registered Nurses can safely provide IUD insertion services to women and this would increase access.(13)

Access to the full range of contraceptive drugs and medical technologies in Australia therefore can be improved by considering the types of healthcare providers who are authorised and trained to provide contraceptives, cost differences and the geographical availability of services providing reproductive and sexual healthcare.

Recommendations:

- increase investment in reproductive and sexual health research
- increase women's involvement in clinical trials, particularly young and adolescent women, to determine the safety, effectiveness, and tolerance of drugs for all consumers
- improve access to the full range of contraceptive drugs and medical technologies in Australia\
- address lack of remuneration for nurses and adequacy of remuneration for doctors as a critical barrier to ensuring the availability of new drugs, devices and novel therapies for consumers

2. Incentives to research, develop and commercialise new drugs and novel medical technologies for conditions where there is an unmet need, in particular orphan, personalised drugs and off-patent that could be repurposed and used to treat new conditions

Incentives are required for researching, developing and commercialising new contraceptives and novel technologies. There is growing global awareness of the need for an expanded range of contraceptives, including non hormonal methods, which can be used by either females or males. Research into novel delivery systems including vaginal ring technologies, intrauterine devices and methods to inhibit sperm production or movement which reduce or eliminate the use of hormones and their attendant risks is increasing around the world. With increasing funding from pharmaceutical companies, not for profit organisations and philanthropy, Australia would be well placed to lead and partner in clinical trials on these innovative products.

Incentives can also be provided for companies to repurpose existing products. For example, some progestogen based drugs including Visanne (2mg dienogest) is currently only licensed for the management of endometrial lesions but not for contraception despite being potentially useful for this indication - because the trials have not yet been done in Australia.

High dose progestogen only pills are also an effective contraceptive for those who are unable to take a combined (oestrogen and progestogen) pill, for example due to having breast cancer, but are unavailable in Australia due to regulatory restrictions

Recommendation:

- provide avenues to develop new contraceptive products and repurpose other products that can be used for contraception

3. Measures that could make Australia a more attractive location for clinical trials for new drugs and novel medical technologies; and

It would be advantageous to become a more attractive country for clinical trials of new and innovative contraceptive products. Clinical trials are perceived as expensive in Australia. Government incentives could act as a facilitator to attract more research.

The HPV vaccine was developed in Australia and has achieved significant health gains, both here and globally. Australia can be strong leaders in developing new drugs and novel medical technologies in the area of reproductive and sexual health.

To achieve greater equity research that includes the participation of women is needed. Further, as an essential area of life, research in the area of reproductive and sexual health should be a priority.

Recommendation:

- prioritise investment in clinical trials for new contraceptive drugs and technologies

4. Without compromising the assessment of safety, quality, efficacy or cost-effectiveness, whether the approval process for new drugs and novel medical technologies, could be made more efficient, including through greater use of international approval processes, greater alignment of registration and reimbursement processes or post market assessment.

Australia is a modern country at the forefront of health delivery, and yet lack of access to pharmaceuticals available elsewhere holds us back from achieving improved health outcomes. Australian people should have the same options in relation to regulated pharmaceuticals for healthcare, as that available elsewhere.

In Australia, we lack access to many of the contraceptives available internationally due to onerous regulatory processes. Further, drugs can take longer to become available in Australia than in comparable countries. For example, the Kyleena (a smaller lower dose levonorgestrel releasing IUD) was launched in UK Feb 2018 and PBS listed here 1 March 2020 here, two years later.

Internationally, the lack of harmonisation between national regulations is slowing down the implementation of international clinical trials. Governments and regulatory authorities are encouraged to share information internationally and co-ordinate policies for clinical trial approvals.(14) The Organisation for Economic Co-operation and Development Recommendation on the Governance of Clinical Trials provides recommendations for harmonising clinical trial regulations across countries and accelerating the rigorous testing of potential treatments.(15)

Examples of contraceptives which Australian women are unable to access and benefit from but which are available in other countries such as the UK are provided below. Anecdotally the onerous approval processes make it unattractive for pharmaceutical companies to bring these products into the Australian market.

High dose progestogen-only contraceptive pills

The desogestrel (Cerazette) progestogen only contraceptive pill is not currently available in Australia, despite being available in UK and NZ. Cerazette is a very effective contraceptive which reliably prevents ovulation and is important for women who can't use oestrogen but prefer an oral method (for example, due to a history of breast cancer or deep vein thrombosis).(16) If used consistently and correctly, progestogen-only pills are more than 99% effective. Currently the only progestogen-only oral contraceptives available in Australia are so called low dose mini-pills which work by thickening the cervical mucus and have a very narrow time frame to be taken each day thereby limiting their effectiveness. The introduction of Cerazette on the PBS would be welcomed by women and their doctors.

Self-administered subcutaneous contraceptive injectable

Sayana Press (Subcutaneous Depot Medroxyprogesterone Acetate) is similar to the currently available Depo Provera but it can be self-administered subcutaneously rather than requiring a visit to a health professional every 3 months for an intramuscular injection. Sayana Press is available in many countries including the UK and would have particular applicability in Australia for women in rural and remote areas who could be prescribed a 12 months supply in order to prevent unintended pregnancies when they are unable to get to a clinic easily. It is also useful for women with obesity and patients at risk of haematoma due to bleeding disorders or anticoagulation due to its subcutaneous route of administration.

The contraceptive patch

The transdermal contraceptive patch is a safe and convenient alternative to the combined oral contraceptive pill available in the UK, US and other countries but is not available in Australia. The contraceptive patch contains the same hormones as the combined oral contraceptive pill (oestrogen and progestogen) and works in the same way by preventing ovulation. When used correctly, the patch is more than 99% effective at preventing pregnancy. It has the advantage of only needing to be applied weekly, and its effectiveness is not reduced for women with chronic gastrointestinal conditions or acute vomiting or diarrhoea. It can be worn in the bath, when swimming and while playing sport.

HIV prevention for women

The WHO recently announced that the European Medicines Agency (EMA) has approved the dapivirine ring (DPV-VR) for HIV prevention for women, paving the way for regulatory approvals for the ring in countries where women could benefit from additional HIV prevention options.(17) The dapivirine ring is intended to be used to reduce the risk of acquiring HIV during vaginal sex for women aged 18 years and over, who are at higher HIV risk, in combination with safer sex practices. The antiretroviral drug dapivirine is released from the ring into the vagina slowly over one month. The ring is made of silicone and is easy to bend and place in the vagina. The monthly dapivirine ring provides women with the first discreet, long-acting HIV prevention choice.

Recommendation:

- improve access to a wider range of contraceptives (that have proven effectiveness and are available internationally) in Australia via changes to regulatory processes.

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