Reproductive and Sexual Health Subcommittee of PTAC
Teleconference held 19 October 2015

(minutes for web publishing)

Reproductive and Sexual Health Subcommittee minutes are published in accordance with the *Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and PTAC Subcommittees 2008*.

Note that this document is not necessarily a complete record of the Reproductive and Sexual Health Subcommittee meeting; only the relevant portions of the minutes relating to the Reproductive and Sexual Health Subcommittee discussions about an Application or PHARMAC staff proposal that contain a recommendation are generally published.

The Reproductive and Sexual Health Subcommittee may:

a) recommend that a pharmaceutical be listed by PHARMAC on the Pharmaceutical Schedule and the priority it gives to such a listing;
b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or
c) recommend that PHARMAC decline to list a pharmaceutical on the Pharmaceutical Schedule.

These Subcommittee minutes have yet to be ratified by PTAC and will be reviewed at its meeting on 5 & 6 May 2016.

Record of the Reproductive and Sexual Health Subcommittee of PTAC teleconference meeting on 19 October 2015

1. Non Latex Male Condoms Funding Restrictions

1.1. The Subcommittee noted a paper by PHARMAC staff requesting advice on proposed Special Authority (SA) criteria for the potential funding of non latex male condoms.

1.2. The Subcommittee considered that the number of patients who may use non latex condoms estimated in the PHARMAC paper was reasonable at 160,000 per year. The Subcommittee further considered that whilst there was variable documentation about the percentage of the population who have a true latex allergy, 1% is an appropriate estimated value to use.

1.3. The Subcommittee considered average usage of condoms to be 1 condom per week per patient.

1.4. The Subcommittee noted that a true latex allergy was uncommon and that whilst unsupported in the literature, a latex allergy seemed to be more prevalent in the younger population of New Zealanders. The Subcommittee considered that developing Special Authority (SA) criteria for access to non latex male condoms was reasonable due to anecdotal growth in the allergy market.

1.5. The Subcommittee **recommended** the following Special Authority for access to non latex male condoms:

Special Authority for Subsidy:
Initial application- from any relevant practitioner. Approvals valid without further renewal for applications meeting the following criteria:
Both:

1. Patient diagnosed with latex allergy; and
2. Any of the following:
   - 2.1 diagnosed by skin prick testing; or
   - 2.2 diagnosed by Radioallergosorbent (RAST) test/Skincap latex blood test; or
   - 2.3 diagnosed by patch testing.

1.6. The Subcommittee considered that skin prick testing as a diagnostic test was widely available in the community. Members further considered that the RAST test and the serum Immunoglobulin E (IgE) test was also available in the community but was a more expensive test. The Subcommittee members considered that whilst patch testing was also available it was difficult and expensive to access this test.

1.7. The Subcommittee noted that patients with a true latex allergy would have a lifetime allergy and therefore Special Authority renewals would be inappropriate.

1.8. Subcommittee members considered that 3-month prescriptions should be for 12 units based on an average usage of 1 per week per patient. Members recognised that

individuals requiring more than 12 units per 3 months would be able to request another prescription within the 3 month period.

1.9. The Subcommittee **recommended** reviewing the SA criteria 1 year after implementation to review SA uptake by prescribers.

1.10. The Subcommittee **recommended** a BPAC article should be written to support the education of medical practitioners regarding what is a true latex allergy.

1.11. The Subcommittee considered that patients with a latex allergy currently had no funded alternative for STI prophylaxis and that their only option is to self-fund non latex male condoms.

1.12. The Subcommittee considered that the data in the Cost Utility Analysis (CUA) provided by PHARMAC underestimated the incidence of chlamydia. The Members further noted that the risk of infection-related complications such as preterm labour and ectopic pregnancies were not included in the PHARMAC Cost Utility Analysis.

1.13. The Subcommittee noted that New Zealand sexual and reproductive health data from the New Zealand Health Survey, which includes sexual behaviour and contraceptive data, would be released at the end of 2015 or early 2016 by the Ministry of Health. The Subcommittee noted that it would be the first time in three decades that any New Zealand general population data would be available on these topics. Members considered this data may be useful to inform review of the SA criteria for non latex male condoms.

2. Female Condoms Funding Restrictions

2.1. The Subcommittee noted a paper by PHARMAC staff requesting advice on proposed Special Authority (SA) criteria for the potential funding of female condoms.

2.2. The Subcommittee noted that PHARMAC was seeking clinical advice about how and by whom female condoms may be used. The Subcommittee noted that there is no data to support the use of female condoms for anal sex. The Subcommittee further noted that there have been reports of use of female condoms for anal intercourse and that this has caused anal bleeding. Subcommittee member's note that this is off label use of female condoms and that they are not FDA approved for anal sex.

2.3. The Subcommittee considered that they were uncertain of the number of patients who might use female condoms, as estimates of patient numbers would be dependent on whether the condoms were used for vaginal intercourse or anal intercourse. Subcommittee members further considered that some women who initially use female condoms would not continue to use them, based on overseas anecdotal information. The Subcommittee considered that numbers of patients, estimated at 1000, who might use female condoms for vaginal intercourse would be reasonable.

2.4. The Subcommittee considered that HIV (Human Immunodeficiency Virus) positive woman do not currently have many choices for contraception as antiretroviral therapies often contraindicate hormonal contraceptives. The Subcommittee considered they were supportive of female condoms being available for women who were HIV positive. Subcommittee further considered that it would be important to provide prophylaxis for

women living with HIV positive partners and the Special Authority criteria should reflect this.

2.5. The Subcommittee considered that some patients with a true latex allergy would benefit from access to non latex female condoms and as this was a lifetime allergy requiring a Special Authority renewal would be inappropriate.

2.6. The Subcommittee considered that female condoms may provide prophylaxis for those patients who may have a high risk of exposure to Sexually Transmitted Infections (STIs) as determined by STI diagnosis in the last 12 months. The Subcommittee further considered that some patients may also have STIs that are subclinical and therefore are undiagnosed. The Subcommittee considered that access to female condoms for this large group of patients via a Special Authority was difficult to determine.

2.7. The Subcommittee **recommended** the following Special Authority for access to female condoms:

Special Authority for Subsidy:
Initial application (patient with a latex allergy) - from any relevant practitioner. Approvals valid without further renewal for applications meeting the following criteria:

Either:
1. Patient diagnosed with latex allergy; and
2. Any of the following:
    2.1. diagnosed by skin prick testing; or
    2.2 diagnosed by Radioallergosorbent (RAST) test/Skincap latex blood test; or
    2.3 diagnosed by patch testing.

Initial application – (patient with HIV) from any relevant practitioner. Approvals valid without further renewal where the patient has a confirmed HIV infection.

Initial application – (HIV positive partner) from any relevant practitioner. Approvals valid for 1 year where the patient has an HIV positive partner.

Renewal – (HIV positive partner) from any relevant practitioner. Approvals valid for 1 year where the patient has an HIV positive partner.

2.8. The Subcommittee noted that female condoms are usually supplied in packs of 3. Subcommittee members considered that 3-month prescriptions should be for 12 units (4 packs) based on average usage of 1 per week per patient.

2.9. The Subcommittee **recommended** a BPAC article should be written to support the education of medical practitioners regarding true latex allergy.

2.10. The Subcommittee considered, there was likely to be a high initial uptake of female condoms but that this may decrease in the long term. The Subcommittee further considered that the PHARMAC cost utility analysis was based on a number of assumptions and therefore it may be appropriate to review of the SA criteria in a year.

2.11. The Subcommittee **recommended** reviewing the SA criteria 1 year after implementation to review SA uptake by prescribers.