27 February 2015

The Hon Sussan Ley, MP
Minister for Health
Minister for Sport
Suite M1 41
Parliament House
Canberra ACT 2600
Sent via email to Minister.Ley@health.gov.au
Cc: CommentsPBAC@health.gov.au

Dear Minister

RE: Health disparities in testosterone prescribing

The National LGBTI Health Alliance wishes to express our serious concerns about the intended change to the Pharmaceutical Benefits Scheme (PBS) Guidelines, as reported in Australian Doctor on 24 February. According to this article, from either 1 March or 1 April 2015, the PBS Authority will bar General Practitioners (GPs) from ‘initiating’ testosterone without the input of ‘a specialist endocrinologist, urologist, member of the Australasian Chapter of Sexual Health Medicine, or in consultation with one of these specialists’.

About the National LGBTI Health Alliance

The Alliance is the national peak health organisation for organisations and individuals from across Australia that work together to improve the health and wellbeing of lesbian, gay, bisexual, transgender, and intersex people and other sexuality and gender diverse (LGBTI) people. We support measures that contribute to improved health and wellbeing for all LGBTI people in Australia.

Formed in 2007, the Alliance has 89 Member Organisations that include the major providers of services for LGBTI people in each state and territory across Australia. The Alliance provides a representative national voice to: develop policy and to support LGBTI health issues; seek increased commitment to services for LGBTI people; develop the capacities of LGBTI organisations; and support evidence-based decision-making through improved data collection covering sexuality, gender identity, and intersex characteristics.

Health disparities in testosterone prescribing

Since the 24 February mention in Australian Doctor of the impending restriction on GPs prescribing testosterone, the Alliance has received numerous expressions of concern from LGBTI community members and from medical and nursing practitioners across Australia about the discriminatory and disastrous anticipated effect of this policy. We outline these concerns as follows.
**Indirect discrimination in healthcare**

From 1 August 2013, the *Sex Discrimination Act 1984*\(^{18}\) has included amendments that prohibit both direct and indirect discrimination on the basis of sexual orientation, relationship status, gender identity, and intersex status in Commonwealth activities. According to the *Act*, indirect discrimination is a situation in which a policy is the same for everyone but places a particular group at a disadvantage; the intent to discriminate is not necessary for a policy to constitute indirect discrimination. This includes access to healthcare services. This important legislation contributes toward an inclusive framework for the implementation of Australian equality values in the delivery of Commonwealth services.

Consequently, the Alliance wishes to inform the Department that the intended restriction on GPs prescribing testosterone will have predictable and disproportionately negative consequences for at least (but not limited to) three populations protected by this legislation:

- men of trans experience (i.e., men who were assigned as female at birth)
- people with non-binary genders (i.e., people who do not identify as women or men, but whose gender affirmation process may include medical intervention), and
- people with intersex characteristics (i.e., people whose physical characteristics are not considered strictly ‘female’ or ‘male’ by modern medical norms; most people with intersex characteristics identify as women or men).

Australian and overseas research documents the medical necessity and resultant health benefits of testosterone for those who seek this medication as part of gender affirmation (i.e., the consensual process of affirming one’s own understanding of one’s gender through social, medical, and/or identity document changes)\(^{3,5,6,7,13}\). Research also documents the negative mental health outcomes that have resulted from restricted access to testosterone\(^{15,19}\). Although testosterone prescribing also affects diverse populations beyond those affirming their genders (e.g., people with prostate or breast cancer and people living with HIV), we focus here on the specific areas of concern raised by some of our member organisations and which fall within our remit as Australia’s peak body for LGBTI health.

When men of trans experience, people with non-binary genders, and people with intersex characteristics seek testosterone as part of a consensual medical gender affirmation (i.e., the process of affirming one’s gender through medical interventions), they typically seek services from a GP whom they trust. The impending policy is likely to interfere with that clinical relationship and substantially reduce equal access to healthcare for these populations. The policy is also likely to increase the risk of harm from self-administration of hormones without medical supervision\(^{15}\).

We are alarmed by the total lack of consultation with people from federally protected, historically marginalised populations when making this substantive policy change. None of our member organisations that expressed concern about this change had been consulted or informed of the changes until the publication in *Australian Doctor*. We encourage the Department and the PBAC to consult with us and with our member organisations in order to ensure that PBS policy does not have adverse impacts that may incur liability under the *SDA*. 

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*SDA*: Sex Discrimination Act 1984

*PBS*: Pharmaceutical Benefits Scheme
Lack of consultation

The exact wording of the intended policy has not been shared publicly, nor has a draft policy document been circulated for discussion or input from those communities that will be directly affected by this policy. The exclusion of these communities from the healthcare policy process appears inconsistent with recent efforts by the Commonwealth Government to bring federal departments into compliance with federal anti-discrimination legislation.

We note that the Diversity in Health Report prepared at our National Health Roundtable was distributed to Commonwealth departments in November 2012. This Report contained a recommendation for the Pharmaceutical Benefits Advisory Committee (PBAC) to review its current regulation of particular medications accessed for medical gender affirmation, with regard to the limitations this places on such people’s capacity to travel, and called ‘for community inclusion on the PBAC on an ongoing basis’. Both the intended policy and the exclusion of our communities from this policy process highlight the ongoing necessity for the PBAC to implement this recommendation.

Lack of adequate preparation

The article in which this policy was announced appeared in print less than a week before the earlier of the two dates stated for its commencement. The speed with which the change is intended to take effect also means that our stakeholders and their health practitioners have had insufficient time to prepare for the predictable problems that are likely to arise.

Lack of clarity

The article used the word ‘initiated’ when describing the requirement for non-GP specialist involvement in testosterone prescribing. However, the article did not clarify whether prescription renewals on the PBS will require non-GP specialist approval in addition to the existing PBS Authority authorisation currently used by Australian GPs, nor whether any specialists from additional medical fields would be permitted to prescribe testosterone without first consulting an endocrinologist, urologist, or sexual health physician.

The current lack of clarity is likely to result in overly strict applications of the policy by cautious medical practitioners, who often have limited knowledge that testosterone is considered medically necessary for consensual gender affirmation. The interaction between a climate of increased scrutiny and the lack of sufficient education about the use of testosterone for consensual gender affirmation in Australian medical curricula is also likely to contribute to the unintended negative consequences of this policy.

If the policy does apply to prescription renewals, this would have obvious implications for all people who are prescribed testosterone on a long-term basis and do not require regular specialist consultation for a GP to identify their need for testosterone. As one non-GP specialist who contacted us to share his concerns stated, ‘Dosing of testosterone is very straight forward; unless someone is presenting with suddenly low testosterone and who therefore might need a diagnosis or regular monitoring shows a problem, there is no need to see a specialist.’ Furthermore, GPs often have more experience prescribing testosterone than urologists, as one Australian urological trainee told us: ‘Most urologists I know do not have much experience with testosterone prescribing. If someone has an orchiectomy, the GP deals with prescribing testosterone if needed. Testosterone is not indicated for most urological conditions, and GPs and endocrinologists typically handle those issues. This policy is really poorly thought out.’
Exacerbating rural health disparities

The requirement to consult with a non-GP specialist when prescribing testosterone will further exacerbate existing health disparities and access shortages faced by people in rural and remote communities, particularly those in underserved Aboriginal/Indigenous and Torres Strait Islander communities\(^9,16\) and people of trans experience living in rural, regional, and remote communities\(^11\). The effect on those communities in which non-GP specialists are unavailable or difficult to access is likely to be immediate and profound. For example, an Australian study of 4,596 specialist doctors found that only 19% provided outreach, of which only 16% involved remote outreach\(^17\). In some as of Australia, people must travel for many hours in order to access basic GP services. As a result of these severe workforce shortages, GPs who provide services in rural and remote communities must often provide care that is more commonly provided by non-GP specialists in well-resourced urban areas (e.g., the phenomenon of rural GP surgeons\(^2,8\),\(^4,9,10,12,14,16,17,20\)). In this climate, it is neither evidence-based nor socially responsible policy to add further restrictions on the healthcare gaps that GPs are able to fill in the absence of adequate access to non-GP specialists.

Services delays and negative health outcomes

The wait times for an appointment with an endocrinologist in some regions can be over 6 months long. The added travel time and financial expense can also be a formidable hurdle for those in rural, regional, and remote areas and those with limited income and limited access to transportation to the nearest specialist. In some cases, the nearest specialist is located many hours away. The requirement for non-GP specialist consultation will lead to service delays and resultant negative health outcomes for those who need testosterone.

Continued misuse of non-GP testosterone prescribing for people with intersex characteristics

As documented in the Senate Report on the Coerced and involuntary sterilisation of intersex people in Australia\(^4\), many people with intersex variations in Australia have experienced coerced or involuntary medical procedures—including but not limited to non-consensual hormonal reassignment—by specialists such as endocrinologists, urologists, and sexual health physicians. For many people with intersex characteristics, their GP is the only medical provider with whom they feel safe from these abuses. As documented in the aforementioned Senate Report\(^4\), these coerced and involuntary medical procedures continue to be practiced routinely by Australian endocrinologists, urologists, and sexual health physicians. Thus the requirement to consult with these specialists will not prevent the misuse of testosterone for medically unnecessary purposes and may detract from the safety, mental health, and comfort of people with intersex variations.

Ineffective and discriminatory policy

Despite creating or exacerbating the problems described above, the intended policy change will not actually prevent the problem it claims to address. GPs are not the only medical practitioners whom research has shown to engage in inappropriate prescribing, as the example of coerced and involuntary medical interventions to ‘normalise’ people with intersex variations illustrates.

The PBS Authority currently permits prescribing of the rejuvenation serum that this change claims to prevent. Merely shifting the prescribing of testosterone to endocrinologists and urologists will retain non-GP specialists’ ability to prescribe medically unnecessary uses of testosterone. Barring the coverage of specific forms of misuse on the PBS would effectively restrict testosterone misuse without creating
unnecessary access barriers for populations with limited access to non-GP specialists and with greater access to and trust for GPs.

The PBS only includes treatment for puberty induction and micropenis for people under 18. In addition to the concerns about coerced and involuntary medical interventions imposed on people with intersex variations, the intended policy does not address the need for people who present in adulthood with requests for treatment with informed consent. One medical specialist informed us that the combination of the new policy and the existing exclusion from the PBS for people over 18 is likely to exacerbate problems faced by patients in rural and remote locations and for those who are prescribed growth hormone treatment or who have not stopped growing by the age of 18.

One medical specialist expressed concerns to us that the current requirement that those prescribed testosterone on the PBS Authority ‘must be male’ may lead to the interpretation by some specialists that people of trans experience and people with intersex characteristics who seek and/or use testosterone should not be covered under the PBS. Although this is an ongoing issue unrelated to the intended policy change, the further restriction of access to testosterone under the PBS is likely to interact with this existing issue to facilitate additional situations of healthcare discrimination. Thus our evidence-based policy analysis leads us to believe it will lead to severely negative health outcomes that inhibit the ability of people who need testosterone to lead contributing lives in Australian society.

**Conclusion**

For these reasons, we urge you to discontinue the intended policy and to retain GP testosterone prescribing without the requirement of consultation with non-GP specialists.

We believe that retaining GP testosterone prescribing is essential to ensure adequate healthcare for all Australians for whom testosterone is medically necessary. We also urge you to consider whether the concerns we have raised may have implications for Department compliance with Australian anti-discrimination legislation that prohibits indirect discrimination.

**RECOMMENDATIONS**

To address the predictable and severe harm that will be caused if the intended policy change to GP testosterone prescribing is implemented, we make seven key recommendations:

- **Recommendation 1:** That the PBAC retain the testosterone prescribing rights of GPs, without the requirement to consult with other specialists.

- **Recommendation 2:** That the PBAC implement the 2012 recommendation from the *Diversity in Health Report* to review its current regulation of particular medications accessed for medical gender affirmation (including testosterone), with regard to the limitations this places on such people’s capacity to travel, and implement community inclusion on the PBAC on an ongoing basis.

- **Recommendation 3:** That the PBAC refrain from instituting policy changes that are likely to have negative health outcomes for population groups protected under Commonwealth anti-discrimination legislation, without first conducting community consultation that investigates the specific needs of these populations and investigating whether the proposed policy changes comply with federal anti-discrimination legislation.
• **Recommendation 4:** That the Commonwealth fund training on the use of testosterone for GPs and other medical specialists to reduce both inappropriate testosterone prescribing and inappropriate refusal to prescribe testosterone. This training should be required for all medical practitioners prescribing testosterone, not only GPs. We stress that this training must be equally accessible to medical practitioners working in rural, regional, and remote areas.

• **Recommendation 5:** That the testosterone prescribing training curriculum should be inclusive and specifically address:
  - The medical necessity of testosterone for men of trans experience and people with non-binary genders who seek testosterone as part of medical gender affirmation;
  - The medical necessity of testosterone for people with intersex characteristics who seek testosterone with their own informed consent—this includes women with intersex characteristics who experience health benefits from consensual and desired testosterone; and
  - The medical and legislative bases for protecting people with intersex variations from coerced and involuntary ‘normalisation’ through testosterone currently prescribed by endocrinologists, urologists, and other medical practitioners.

• **Recommendation 6:** That the PBAC act to prevent ongoing testosterone misuse for medically unnecessary purposes by enacting the Senate Committee recommendation to ban the non-consensual use of hormonal interventions to ‘normalise’ people with intersex variations. This includes the ongoing coerced and involuntary use of testosterone by endocrinologists, urologists, sexual health physicians, and other medical practitioners routinely practiced across Australia today.

• **Recommendation 7:** That the PBAC further address testosterone misuse for medically unnecessary purposes by barring coverage from specific forms of misuse on the PBS. This would directly address concerns about inappropriate prescribing by medical practitioners from all specialties, without restricting the ability of GPs to meet the needs of patients from historically marginalised and geographically underserved populations for whom GPs may be best positioned to prescribe.

We appreciate this opportunity to raise our serious concerns about the severe harm that will likely result from the intended changes to testosterone prescribing. As Australia’s national experts on LGBTI health policy, we thank you for taking the time to consider these concerns. We encourage you to contact the Alliance’s Manager of Research and Policy, Dr Gávi Ansara, to discuss the issues identified in this submission. He can be reached by email at gavi.ansara@lgbtihealth.org.au or by phone at (02) 8568 1110.

Yours sincerely

Rebecca Reynolds
EXECUTIVE DIRECTOR

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REFERENCES


