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Mr. Ray Chepesiuk, Commissioner
Pharmaceutical Advertising Advisory Board
375 Kingston Rd., Suite 200
Pickering, Ontario L1V 1A3

June 22, 2011

Dear Mr Chepesiuk,,

We are writing to lodge a formal complaint about an advertising campaign by Abbott, aiming to stimulate sales of its testosterone gel, Androgel. This campaign consists of an advertisement that has been running in the Globe & Mail June 6 to July 12. It is accompanied by promotion to physicians and by a Canadian-based website: www.lowT.ca [see attached files with advertising materials].

Not only is the message in this advertisement in contravention of the Food & Drugs Act, it has serious potential to lead to harm to public health, it provides misleading and inaccurate information that would not withstand any serious test of truth in advertising, and it is likely to lead to unjustified increases in health care costs, the latter by promoting testing of men unlikely to be suffering from hypogonadism. By redefining this condition to include signs of normal ageing, Abbott is promoting this product for an unapproved use – normal age-related changes in testosterone levels.

The likely result of this campaign is more false than true positive tests for male hypogonadism. In addition to misleading the public, this is likely to be associated with increased costs for physician visits, testing and drug treatment that are unlikely to lead to health benefits and have a considerable potential for harm. Provincial governments will be footing a large part of this bill.

1) Promotion of unapproved uses

Androgel (testosterone gel) is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone (hypogonadism). It is not indicated for symptoms of male ageing or for normal, age-related declines in testosterone levels.

The advertisement features the headline, “Has he lost that loving feeling?” and in large text, “lack of energy” and “low sex drive.” It calls on readers to contact their doctors and obtain a test for testosterone if they experience these things. The website includes a 10-question quiz that similarly calls on the reader to visit their doctor and ask about a testosterone test even if they exhibit only such non-specific symptoms as ‘falling asleep after dinner’ (who doesn’t?),

or “deteriorating work performance.” The impression provided is that low testosterone is a likely cause and that testosterone treatment is an effective cure.

The ad and website are also misleading in what they leave out: they do not provide information on the most likely causes of late onset male hypogonadism, such as radiation therapy or chemotherapy, prostate surgery, injury to the testicles, or other likely medical causes. The e-mail to physicians cites a highly inflated rate of male hypogonadism of over 38%, which is sure to include many men with healthy gradual age-related reductions in testosterone levels.

2) Potential harm to public health

Last year a study of testosterone replacement in older men that was published in the *New England Journal of Medicine* was stopped early because of increased rates of cardiovascular adverse events.¹ In this study 23/106 (21.7%) of the men on testosterone versus 5/103 (4.9%) on placebo experienced a cardiovascular adverse event, an increase in 16.8%, $p=.0004$ (Fisher’s exact test) over a 6 month period. In other words this is highly unlikely to have been a chance finding. It sends a strong signal that testosterone therapy may be associated with considerable increases in cardiovascular risk. These men were 65 or over and had limited mobility. They were at higher risk for cardiovascular events at baseline than healthy men aged 40 to 64. However the large increase in risk observed in this study sends a strong signal for caution in the use of testosterone replacement. The ad targets men who are overweight and who have type 2 diabetes. These groups are already at high risk for heart disease, and may be at extra risk for harm.

Testosterone use has been associated with a range of adverse events, including increased risk of edema, progression of subclinical prostate cancer, hypertension, and increased haematocrit levels.² A systematic review of clinical trials of testosterone therapy found that men treated with testosterone had lower levels of HDL (“good”) cholesterol, and had over three times the risk of developing erythrocytosis as those on placebo or no therapy.³ This is a likely biological mechanism for the observed increases in the risk of heart disease and stroke described above.

3) Exaggerated implied effectiveness

The advertisement misleadingly implies that if a man’s testosterone is tested, found to be low, and treated with testosterone therapy, his sexual problems will be solved. A systematic review of the effects of testosterone replacement failed to find a difference in sexual satisfaction or in depression.⁴ Similarly, there is no reliable evidence of an effect on cognition.²

4) Disguised advertising of a prescription-only medicine

This is disguised direct-to-consumer advertising of a prescription-only drug. Neither Abbott’s name nor the brand name appears in the advertisements aimed at the public (website + Globe & Mail ad), yet the message is part of an advertising campaign aiming to stimulate Androgel (testosterone gel) sales, as is apparent both from the consumer-directed advertisements and in the e-mail to physicians. In addition to contravening Canadian law, this advertisement contravenes international ethical criteria governing drug promotion. As a UN Member State, Canada supports the implementation of the *WHO Ethical Criteria for Medicinal Drug Promotion*. One of the provisions is that, “Promotional material should not be designed so as to disguise its true nature.” By failing to inform readers that this advertisement is from Abbott,

manufacturer of Androgel, this advertisement disguises its true nature as part of a marketing campaign for a pharmaceutical.

All three components of the advertisement (printed ad, website and ad to physicians) meet the Food & Drugs Act definition of an advertisement: “any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device.”

All components also contravene the deception clause in the Act, *Section 9 (1)*: “No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.”

Additionally, this is disguised direct-to-consumer advertisement of a prescription-only product, and as such it contravenes the following sections of the Food and Drugs Act):

- *Section C.01.001A* No person shall advertise a drug for sale to the general public if that drug contains any of the substances listed in the schedule to Division 10 (proprietary medicines).
- *Section C.01.044*. Where a person advertises to the general public a Schedule F Drug [*prescription-only*], the person shall not make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug.

We ask you to take immediate action to require Abbott to discontinue all components of this advertising campaign.

Thank you in advance for considering this matter.

Sincerely yours,



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The Honourable Leona Aglukkaq, P.C., M.P., Minister of Health, House of Commons, Ottawa, Ontario K1A 0A6, Aglukkaq.L@parl.gc.ca

The Honourable Libby Davies, M.P., Opposition Health Critic, House of Commons, Ottawa, Ontario K1A 0A6, Davies.L@parl.gc.ca

Encl: Globe & Mail advertisement
e-mail to physicians (in two files, screenshot)
Screen shot of promotional website: www.lowT.ca

References

¹ Basaria S, Coviello AD, Travison TG, et al. Adverse events associated with testosterone administration. *N Engl J Med* 2010; 363:109-122.

² Testosterone for 'late onset' hypogonadism in men? *UK Drugs and Therapeutics Bulletin* 2010; 48 (6): 69-72.

³ Fernandez-Balsells MM, Murad MH, Lane M et al. Adverse effects of testosterone therapy in adult men: a systematic review and meta-analysis. *Journal of Clinical Endocrinology & Metabolism* 2010; 95 (6): 2560-2575.

⁴ Bhasin S et al. Testosterone therapy in adult men with androgen deficiency syndromes: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab* 2006; 91: 1995–2010.