

Statement on Generic Oral Contraceptives

This Policy Statement has been prepared and approved by the Executive and approved by the Executive and Council of the Society of Obstetricians and Gynaecologists of Canada.

The Society of Obstetricians and Gynaecologists of Canada welcomes the increased choice available to women provided by the introduction of generic oral contraceptives into Canada. Health Canada has approved new generic oral contraceptives as bioequivalent to currently available brand name formulations, providing increased choice and less expensive options to many Canadian women in need of contraception.

To qualify as bioequivalent to existing brand name formulations, new generic oral contraceptives are required to meet a standard of 80% to 125% blood equivalence.¹ At this time, generic formulations have no Pearl Index rating, the accepted standard for evaluating the effectiveness of a contraceptive method.²

Health care practitioners will continue to prescribe oral contraceptives to best meet their patients' needs, determining which product is most appropriate for each woman. When a specific oral contraceptive product is prescribed, the SOGC believes that no substitution should be made by

a pharmacist without notice to both the patient and her health care provider. When a brand name and generic drug are not clinically equivalent, the decision to switch from brand name to generic oral contraceptive, or vice-versa, could have negative results, including reduced effectiveness or adherence, as well as side effects.

The SOGC encourages members to stay abreast of new developments as we gain Canadian experience with new contraceptive options.

Finally, the SOGC stresses that oral contraceptives, whether generic or brand name, do not provide protection against sexually transmitted infections. For this reason, the SOGC strongly recommends that Canadians consider the use of dual protection, including condoms.

REFERENCES

1. Guidance for Industry: Conduct and Analysis of Bioavailability and Bioequivalence Studies—Part A: Oral Dosage Formulations Used for Systemic Effects. Ottawa: Health Canada; 1992. Cat no. H42-2/56-1992E. Available at: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/bio-a_e.pdf. Accessed November 29, 2007.

2. Product Monograph: PrAVIANE™ 21 and PrAVIANE™ 28 Levonorgestrel and Ethinyl Estradiol Tablets. Barr Laboratories Inc., 2007.

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