

April 19, 2013

The Honourable Leona Aglukkaq, P.C., M.P.
Minister of Health
House of Commons
Ottawa, ON K1A 0A6

Dear Minister:

We are writing on behalf of the Society of Obstetricians and Gynaecologists of Canada (SOGC) and the College of Family Physicians of Canada (CFPC). These two organizations represent over 35,000 health care professionals, and provide more than 95% of all contraceptive care to Canadians.

We want to express our dismay over the debacle of faulty birth control packages reaching consumers in Canada. It represents a breach of immense proportions to individual women, their partners and families, and seriously erodes the public's confidence in what has been, until now, a very reliable contraceptive choice.

While we applaud your decision to launch an inquiry into the undue delay in notifying women and their health care providers, the SOGC and the CFPC urges this inquiry examine Health Canada's delay in issuing a recall, as well as the actions of the manufacturer. The inquiry must address when both HC and Apotex became aware of the problem, and what steps they took to protect the Canadian public. It is imperative that the Canadian public's confidence in the system be restored.

The SOGC and the CFPC are therefore proposing four recommendations to be implemented immediately:

1. Immediate Product Recall Notification

From what we have been able to learn through the media, Apotex was aware of this product deficiency from as early as April 3. Health Canada did not send out a Class 2 recall notice until three days later; the Class 1 recall was not issued until three days later, April 9. Had women been notified immediately on April 3, there were appropriate actions they could have taken, in particular, the use of a back-up method of contraception, or the use of an emergency contraception. Either of these measures could have prevented unplanned and/or unwanted pregnancies - pregnancies that can have life-long and life-altering consequences for men, women and children.

The reasons offered by the Health Canada spokesperson for the delay are completely unacceptable, and suggests a lack of understanding of the importance of reproductive freedom and choice to Canadian women. This principle is fundamental to the members of both the SOGC and the CFPC.

Together the CFPC and the SOGC urgently requests that Health Canada mandate immediate public notification if and when flaws are brought to light that impair effectiveness of any licensed contraceptive product. Regardless of the reasons that led to delays in the Alysena case, such a requirement must be enacted immediately. This requirement must be binding on the manufacturers and Health Canada and/or any of its agencies.

2. All Pharmaceuticals Must Adhere to Same High Standard - Brand Name or Generic

The SOGC and the CFPC request that Health Canada hold all pharmaceuticals to the same high standard, whether they are brand name or generic medications. While we respect the economic benefit to the Canadian health care system of generic medications, this economic benefit cannot be achieved at the expense of quality. It is unacceptable that any birth control pills could be manufactured for the Canadian marketplace without adequate quality control. Contemporary contraceptive tablets have an extremely low dose of hormone in each tablet, leaving little room for error in preparation and use. Canadian women and their partners have a right to expect proven levels of quality and effectiveness through the use of accepted tests.

Supply chain shortage is a further quality control concern that members of the CFPC and the SOGC have experienced. Women are routinely switched from one generic tablet to another by the pharmacist because of supply shortages. There is good medical data that demonstrates a woman's risk of serious blood clots goes up each time she is switched from one contraceptive pill to another; thus while switching for medical reasons may be necessary and justified, switching for manufacturer's supply chain management deficiencies is not.

3. Disclosure of a Generic Substitution

The SOGC and the CFPC request that Health Canada ensures that disclosure of a generic substitution be mandatory – that is, disclosure to both the patient and her health care provider should a substitution be made by a pharmacist. Women must know what tablet they are taking. It is entirely likely that most women and their doctors would not have known that they were taking the faulty Alysena pills. A physician/nurse/midwife's prescription may, in many provinces, have been substituted to a generic formulation without informing the patient or her physician. Women should have the option of paying a fair fee for the brand name drug if that is her preference.

4. Regulation Against Look-Alike/Sound Alike Branding of Generic Medications

The SOGC and the CFPC request that Health Canada institute measures that ensure that generic medications are subject to a similar rigorous review of their packaging (as to their look-alike, sound-alike branding, etc.) as reference medications. A patient might mistakenly make the assumption that this was the oral contraceptive her doctor had ordered, particularly since it looks and sounds like the brand name drug. It is unacceptable that many women did not realize that they were on Alysena because the packaging and branding looks and sounds like the tablet their physician had discussed with them in the office. On the other hand, many women on Alesse or Linessa were of the mistaken belief that they were on the recalled drug. To guard against this potentially devastating confusion, the SOGC and the CFPC

strongly recommend that generic drugs be prohibited by regulation from adopting look-alike, sound-alike 'brand' names, but be identified by their generic medical ingredients.

The SOGC and the CFPC endorses these four recommendations as a means to ensure that this appalling situation is not repeated, and that a more timely response will happen should there be any short fall in quality in years to come. It is imperative that Health Canada put in place an open, transparent system that will restore the confidence of the Canadian public in their contraceptive options.

Sincerely,



Jennifer Blake, MD, BSc, FRCSC, FSOGC
Chief Executive Officer
The Society of Obstetricians and Gynaecologists of Canada



Francine Lemire, MD, CCFP, FCFP, CAE
Executive Director and Chief Executive Officer
The College of Family Physicians of Canada

cc: Dr. Douglas Black, President, The Society of Obstetricians and Gynaecologists of Canada
Dr. Jamie Meuser, Director, Continuing Professional Development/Continuing Medical Education, CFPC
Mr. Eric Mang, Director, Health Policy and Government Relations, CFPC