Position Statement on Isotretinoin

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Isotretinoin has been available in Canada since 1983. It has shown efficacy in cystic and recalcitrant acne, as well as the prevention of acne scarring. However, because isotretinoin is a teratogen and has significant adverse effects associated with its use, it should be reserved for patients with severe nodular and/or inflammatory acne, acne conglobata, or recalcitrant acne, who are unresponsive to conventional therapy, including systemic antibiotics.¹

Currently in Canada, there are means to achieve safe and effective management of isotretinoin through risk management programs (RMP), including the Pregnancy Prevention Program, unique packaging, and educational programs for both patients and health care professionals.

In May 2005, the Canadian Expert Advisory Panel on isotretinoin met and determined that Canada does not need to follow in the footsteps of the US and create a registry of patients taking this medication.² Many dermatologists agree, citing the increased paperwork and inconvenience for patients, physicians, and pharmacists, not to mention the patients who could be denied a potentially helpful medication, which in turn could have serious psychosocial consequences.

In the US on August 8, 2005, the Food and Drug Administration (FDA) approved a different risk management plan for Accutane and generic isotretinoin, in an attempt to reduce the chance that females do not become pregnant while taking the medication. The new plan is called iPLEDGE.³ The plan will be effective as of December 31, 2005 and requires that wholesalers who distribute isotretinoin, the doctors who prescribe it, pharmacies that dispense it, and the patients who take it, must register and agree to carry out the program. By March 1, 2006, only prescribers registered and activated in iPLEDGE can prescribe isotretinoin and only patients registered and qualified can be dispensed the medication. iPLEDGE pharmacies must obtain authorization from the iPLEDGE system before filling any Accutane prescription. If the registered patient is a female of child-bearing potential, the authorization will be based on current and valid negative pregnancy test results.

In light of the recent changes made by the American FDA to the product monograph and the initiation of the iPLEDGE program, it has been suggested that Canada may need to make changes to the current system of management of isotretinoin, especially now that Canadians have access to generic isotretinoin.

The current Accutane Prevention Program (PPP)⁴ in Canada consists of 5 components, including comprehensive information about the potential risks of Accutane, information on birth control options, the Pregnancy Prevention checklist for patients, patient consent form, and a treatment checklist for physicians.

Based on recommendations made by the Canadian Science Advisory Panel on isotretinoin,² the Pharmacy and Therapeutics Committee of the Canadian Dermatology Association suggest that current risk management programs, including the Accutane Pregnancy Prevention Program should be amended to contain:

1. An expansion of the physicians’ checklist to include the lists of potentially interacting medications and herbal therapies;
2. An update to the current consent forms;
3. A toll-free number that both patients and healthcare providers can contact for information;
4. A website with particular attention to making sure that there is information available on isotretinoin and contraception;
5. An education program for family doctors and pharmacists;
6. Pregnancy testing at patient visits (schedule of testing may need to be revised);
7. As generic versions of isotretinoin get introduced, the generic companies should be obligated to have equivalent risk management programs (RMPs); furthermore, all drug companies should continue to provide the RMPs.

With the advent of additions by the FDA to the adverse events section including suicidal thoughts or actions, the Science Advisory Council has also recommended that the information to patients should be revised to better assist in their ability to recognize the signs of depression. Suggested changes include terminology that is more sensitive to the situation and a list of questions.² The panel felt that the warnings to prescribers are adequate; however, despite a lack of definitive data proving a cause and effect relationship between isotretinoin and suicide, there are enough case reports and conflicting opinions to warrant an added educational component relating to the neuropsychiatric events.² Nevertheless, patients with depression who need isotretinoin should not be denied the medication, but that some guideline needs to be developed to deal with this matter.

With Canadian patients now having access to generic isotretinoin, it is even more important that in addition to the physicians and pharmacists, it should also be the responsibility of the manufacturer to ensure that the risk management programs for isotretinoin be appropriately implemented and maintained.

References

2. Science Advisory Panel on Isotretinoin meeting held by Health Canada. 5-12-2005.