

Getting SMARTer?

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For those of us who have seen the restrictions on isotretinoin growing tighter and tighter, more tightening is on the way with a new program in the works for 2005.

S.M.A.R.T.[™], the first risk-management program, was implemented in 2002. Also known as S.P.I.R.I.T.[™], A.L.E.R.T.[™], or I.M.P.A.R.T.[™], depending on the brand of isotretinoin, the program has several cornerstones: pregnancy tests, 2 forms of contraception, a qualification sticker on the prescription, survey participation, patient consent forms, a letter of understanding signed by the physician, and education.

Why the new program? It was revealed at a February 2004 US Food and Drug Administration (FDA) advisory committee meeting that compliance with the elements of the risk-management program has not been universal.¹ In fact, Roche Pharmaceuticals, one of the manufacturers of the drug, found that documented cases of pregnancy among isotretinoin users actually increased after S.M.A.R.T. was implemented. In all, Roche received 150 case reports of pregnancy before S.M.A.R.T. implementation and 183 afterward. The company attributed the increased number of cases to better reporting but suggested revisions to S.M.A.R.T. that would help the program reach its intended goal.¹ Although there was a slight decrease in the number of women who were already pregnant before starting isotretinoin, no improvement was reported in baseline pregnancy testing, monthly pregnancy testing, or birth control methods.² It also was revealed that patient participation in the voluntary survey was significantly below the 60% enrollment forecast by Roche. Absolute participation increased from 16% to 19% in the year prior to S.M.A.R.T. to 22% to 26% during the first year.²

Qualification stickers were used in more than 90% of prescriptions. The FDA is concerned, however, by the 9% of patients who reported they had

a sticker but had not undergone the required pregnancy testing.²

On November 23, 2004, the FDA announced the strengthening of the risk-minimization action plan (RiskMAP) for isotretinoin. Under this plan, the sponsors' new program will include, but will not be limited to, the following³:

1. Registration of all prescribers, patients, and dispensing pharmacies will be registered in a single centralized "clearinghouse."
2. Before a registered pharmacy first dispenses the medication for a particular patient, the following will occur:
 - Completion of patient education by the prescriber
 - An appropriately timed and documented negative pregnancy test prior to dispensing the medication
 - Completion of the informed consent, education, and risk-management components by the patient
 - Electronic or other verification of the above actions
3. For all subsequent prescriptions, the following will occur monthly:
 - Ongoing patient education by the prescriber
 - Repeated negative pregnancy test within a specified window prior to dispensing
 - Completion of the education and risk-management components by the patient
 - Electronic or other verification of the above actions

The positives of the new plan include the following: unification of 4 identical risk-management programs into one; potential to drastically reduce or eliminate pregnancies; increased survey participation; change in behavior of physicians, pharmacists, and patients who have not complied with current rules; assurance that only qualified physicians will prescribe; and, most importantly, assurance that we

CONTINUED FROM PAGE 83

will keep this drug for those severe acne patients who need it.

There also are several potential negatives. No program will likely reduce pregnancies to zero; some baseline number of pregnancies always will be present. There will be an increase in administrative details and possibly an increase in internet and foreign sales as patients become frustrated with a more restrictive system. The worst consequence would be that patients who need isotretinoin may not be able to obtain it. Many physicians may decide to no longer prescribe the drug as the process becomes more cumbersome.

So stay tuned. The American Academy of Dermatology has kept its membership well updated and is actively engaged in the development of the new program. Whatever the final outcome of this process, I urge everyone to stay committed to the

treatment of acne and to make the extra effort to provide isotretinoin to those who need it.

REFERENCES

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