

Electronic Mail Message

32

Date: 07/16/2001 9:14:15 AM
From: Marilyn Pitts (PITTSM)
Subject: Re: Accutane Educational Program Input

Kathy,

I'm mis-termining the action that was taken in January. You are right, only certain lots were pulled (the old lots without the updated product information on psychiatric events).

However, if the current packaging does not meet the requirements of the new labeling at the time of approval of the PPP, can the product be recalled for "misbranding" (or appropriate term)? This would certainly increase the importance in the minds of health care professionals and may increase compliance with the new PPP. In addition, a fixed date will be established to measure the impact of the change. I suspect that a temporary removal of the product from the market for such a serious issue as birth defects would not be life-threatening to a current user.

In addition, the more I think about it, the more I believe that if the product isn't relabeled, and re-packaged with the med-guide in the package, and implementation to occur on a given D-Day (so to speak) then it may appear that we do not think the issue is serious enough. And if we appear not to think the issue serious enough, then it may be difficult to get the health care community to believe the issue is serious enough.

mpitts

>Hi All

>

>Marilyn has presented below VERY interesting idea to improve compliance with

>new PPP when it happens...please take a look so we can discuss it at next

>get together.

>

>Marilyn...one note...I am not aware of any "recall" for placement of the

>MedGuide. In fact, the reason it was distributed as tear off pads instead of

>putting it into the patient package was to avoid having to do a recall when

>it is amended for revised RM plan. Are you perhaps referring to the

>November/December "package exchange" whereby HLR voluntarily exchanged

>in-stock packages so that the patient info on box would all be the same (HLR

>changed the info to be compliant with the May 2000 labeling revision).

>

>Kathy

>—Original Message—

>From: Beitz, Julie G

>Sent: Friday, July 13, 2001 8:49 AM

>To: Pitts, Marilyn

>Subject: Re: Accutane Educational Program Input

>Sensitivity: Confidential

>

>

>Marilyn,

>

>Thank you for these comments. I have no problem with you sending your
>comments on to the 540/ODE 5 folks for their consideration. I was not
>aware of the recall, they may not be either. I suspect this was done
>voluntarily by Roche, but we probably need to know more about it. I do
>like the idea of an official launch date.

>

>Julie

>

>

>>Julie,

>>

>>These are my thoughts on the Accutane educational program. I'm
>>sending
>>them to you instead of Kathy. I can send them directly to Kathy if
>>you
>>desire.

>>

>>I agree that education is an important part of the PPP. It is
>>difficult

>>to prove that education alone will result in a major change in
>>prescribing behavior for a drug that has been on the market for 18+
>>years. However, it is unthinkable not to continue to try to educate
>>the

>>health care community on the teratogenic effects of isotretinoin.

>>There

>>will be some prescribers who will change behavior (it may be difficult
>>to measure the impact).

>>

>>I believe there is merit in placing in the labeling the endorsement of
>>isotretinoin-teratogenicity education (not Accutane) to try to effect

>>

>>prescribing change.

>>

>>I recommend that Roche try to make the educational element in
>>digestible

>>bit sized components. A one to two paged focused picture + brochure
>>with bulleted points on the actual teratogenicity of isotretinoin can
>>be

>>a powerful educational tool. Busy professionals may not have the time
>>to engage in in-depth binders and handouts. Roche's current
>>comprehensive program should still be offered for those who want to
>>participate.

>>

>>My thoughts on the transition:

>>

>>I am somewhat dismayed by the lack of compliance with the current
>>Accutane Medguide requirements in the two pharmacies that I

>>unofficially

>>called. It is dismaying that the pharmacy managers did not know the
>>name of the Medguide by medguide (one did recognize the document after

>>

>>I
>>faxed it to her).

>>

>>I'm concerned that the current state of knowledge will result minimal
>>compliance with the actual sticker program. After thinking about
>>this,

>>I would like to suggest the following for thought:

>>

>>In January, Accutane was recalled for the placement of the MedGuide. I
>>do not know under what regulatory statute the recall occurred. Is it
>>possible to recall all supplies of Accutane a short time before the
>>implementation of the enhanced PPP/Sticker program (maybe one month
>>prior to implementation of the enhanced PPP).

>>

>>I believe this would serve two things:

>>

>>-- The pharmacy community will be placed on alert that new dispensing
>>requirements for Accutane will shortly be implemented. If we
>transition

>>to implementation then some Pharmacists may believe it to be optional,
>>may not get the information, and after the furor dies down, those who
>>did not comply will believe that compliance is unnecessary. Removal
>>from the market on a temporary basis will get every one's attention.
>>And will notify everyone of the impending change in dispensing
>>requirements.

>>

>>-- A scheduled, tangible day of implementation will be firmly
>>established in the health community's mind. As of such and such date,
>>isotretinoin will be dispensed by pharmacies with the sticker system
>>only, will not be automatically refillable, and will be dispensed in
>>accordance to criteria detailed in the product labeling. This is
>>necessary for the safe use of the product. If a firm date of
>>implementation is not established, compliance may be severely
>>compromised. I base this on the current distribution of the Accutane
>>mandated medguide.

>>

>>— This is a public health concern. Isotretinoin's teratogenicity is
>>equivalent to thalidomide. We will not jeopardize anyone if
>>isotretinoin is removed from the market to bring it into label
>>compliance. Also, I strongly endorse the placement of the Accutane
>>MedGuide in the product packaging. The birth control people are able
>to

>>perform this feat, I don't see why Roche cannot. I also believe that
>>the Medguide should be in the product packaging at the time of
>>implementation of the sticker system.

>>

>>Just some food for thought,

>>

>>Thanks,

>>

>>Marilyn

>>

>>

>>