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BCC: CN=Jared G Kerr/OU=AM/O=LLY

Date: 03/27/2002 11:15:49 AM

From: CN=Jared G Kerr/OU=AM/O=LLY

Subject: Re: Japan: Glucose -- Teleconference Review

FYI. Review of teleconference on possible labeling changes to Japan PI for olanzapine (March 26, 2002 (Indy)).

Attendees

Indy

Patrizia Cavazzoni
Jared Kerr
Jim Gahimer
Alan Breier

Japan

Yasushi Ito
Anne Bille
Noriko Akagi
Ichiro Obi
Akira Kokan
Keiichi Enomoto
Hiromasa Tara
Yoshiki Kaneiwa
A J Wood

Label

1. Precautions

1. Careful Administration
- (1) Patient with...

Japan: Proposed new text may prevent new statement in "CONTRADICTIONS" section of label and/or "Doctor Letter"
Indy: Agrees to additional text

2. Precautions

2. Important Precautions

(1) "DM statement"

Japan: Two versions of text proposed. One with blood glucose monitoring and other statement without.

Note: Both statements should contain "Administer olanzapine, with sufficient observation of the patient status..."

Indy: Prefers text **without** statement on blood glucose monitoring. Emphasis should be on monitoring for ALL risk factors for DM. Ito-sensei agrees that monitoring statement could have multiple negative effects.

(2) "Weight Gain"

Movement of "DM statement" before "Weight Gain" statement is agreeable for both Japan and Indy.

3. Adverse Reactions (Clinically Significant Adverse Reactions)

...3) "Hyperglycemia"

Japan Proposed New Text: (from redacted Japan Diabetic Assoc. guidelines)

"When hyperglycemia continues without treatment, there is a fear of serious outcome. If thirst, excessive drinking, polyuria, nocturia, rapid weight loss, polyphagia and fatiguability etc. occur, consider a possibility of hyperglycemia and take appropriate measures such as diet therapy, exercise therapy and pharmacotherapy.".... "including some fatal cases."

Indy Changes:

"If ~~When~~ hyperglycemia continues without treatment, there is a fear **potential** of serious outcome. If thirst, excessive drinking, polyuria, nocturia, rapid weight loss, polyphagia and fatiguability etc. occur, consider a possibility of hyperglycemia and take appropriate measures such as diet therapy, exercise therapy and pharmacotherapy."... "including some fatal cases."

Education

Medical Liaison

Program has not been successful in Japan because the role of medical representatives (sales rep) is defined to provide medical

information.

Japan Affiliate Program

Increase GMC frequency

Increase Speakers Training Frequency ("Train the Trainers" Program: 80 psychiatrists already have attended)

may be possible Use of 3rd party may not work unless very independent. Working with an organization like Japan psychiatry association since they would act for all companies and thus Lilly could not influence.

Improve MR education

Indy Suggestions

During DM discussion add messages about prolactin, TD, etc. and overall positive safety and efficacy profile

Schedule

1. March 27: Meet with Japan Affiliate Labeling Committee for approval of changes to PI
2. March 27: Fax draft label to MHLW
3. March 28: Establish meeting time with MHLW
4. March 29, 2002 5 PM: MHLW meeting (Tokyo)

Sincerely,

Jared Kerr
Critical Issues-Customer Response Team
Zyprexa Product Team

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