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Additional Comments	
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**Information regarding
ZYPREXA European Label**

Situational Overview

Early last week, the UK regulatory agency reported in its quarterly newsletter a language change with respect to appropriate clinical monitoring of patients with diabetes in the ZYPREXA European label which took place more than a year ago. Since December 2000, the European label has contained language consistent with the information contained in the US label.

On May 3, an article referencing the UK regulatory agency report appeared in Reuters News, inaccurately characterizing the language change in our European label as having taken place recently. The article appears to suggest causal relationship between Zyprexa and hyperglycemic events; this is not an accurate reflection of the European label or of current scientific understanding. In addition, the article does not provide critically important context, such as: 1) the very high prevalence of diabetes in severely mentally ill patients that has been identified for decades; 2) the reports of treatment-emergent diabetes during treatment with most current and past antipsychotic medications; 3) the evidence from multiple epidemiology studies that identified comparable rates of treatment-emergent diabetes across commonly prescribed antipsychotic agents, and; 4) that ZYPREXA has now been used in 8 million patients world wide, with a very favorable track record of safety and efficacy.

Subsequently to the publication of the Reuters article, Bloomberg (a financial news agency) also published an article referencing the UK regulatory agency's report. The article quotes an analyst at Deutsche Bank Securities Inc. as stating, "Other drug makers will be able to use this, and that's a challenge Lilly faces now." The analyst then states, "This is an issue that has been around for a while, and I think doctors know it's a risk, but that many feel it's the most effective drug."

Good clinical practice suggests that psychiatric patients should be evaluated for the development of diabetes, as should the general population, based on risk factors defined by the American Diabetes Association and World Health Organization. Given the vast evidence that the risk of diabetes is comparable across widely prescribed psychotropic agents, concerns regarding diabetes should not be a differentiating factor in treatment selection. The primary consideration for choosing a psychotropic agent continues to be its overall risk/benefit profile, i.e. its efficacy in treating the psychiatric illness at hand and its overall tolerability. It is our obligation to let our customers know not only that ZYPREXA is safe, but that to not prescribe based on a fear of diabetes would be to potentially deny patients the best available medication to move their lives forward.

Patients and health care providers must be careful in interpreting news reports like the one published by Reuters because taken out of context they could potentially endanger the health and safety of patients suffering from severe and persistent mental illness.

Sales Force Role

We will only reach our goals by “fueling our customers’ passion that Zyprexa is extraordinary,” so we are asking you to continue to confidently deliver the comparable rates message and utilize the verbatim below only in response to a customer inquiry or concern only utilize this verbatim if a customer asks a question about our label in Europe or the Reuters article.

Sales Force Verbatim

- Early this/last week, the UK regulatory agency reported in its quarterly newsletter a language change with respect to appropriate clinical monitoring of patients with diabetes in the ZYPREXA European label which took place more than a year ago. Since December 2000, the European label has contained language consistent with the information contained in the US label.
- As you know, we support the ADA guidelines that for patients with diabetes, or significant risk factors, good clinical practice includes assessment and follow-up regardless of what agent a patient is receiving.
- On May 3, an article referencing the UK regulatory agency report appeared in Reuters News. It inaccurately characterizes the language change in our European label as having taken place recently.

➤ ZYPREXA offers unsurpassed efficacy in schizophrenia and bipolar mania with a very favorable side effect profile.

Q & A
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Q: What are the changes that have been made to the European label for ZYPREXA and when did they occur?

A: Several changes to the EU label have taken place since launch as a result of routine label reviews by the CPMP.

➤ Following a routine review in 12/98, the CPMP requested that the label include language on “appropriate clinical monitoring” in diabetic patients and in patients with risk factors for the development of diabetes. This change took effect in 7/99.

➤ Following our submission of an updated data package that included our glucose data, the CPMP requested that the label be further amended to include a reference that “ketoacidosis or coma . . . has been reported very rarely, including some fatal cases.” (Note that “very rarely” refers to a reporting rate of less than 0.01%.) This change took effect in 12/00; due to the time required to perform and implement all translations necessary and to complete printing by each European affiliate, the updated label first appeared in the marketplace in 11/01.

The language contained in the European label for ZYPREXA is consistent with the information contained in the US label.

The sort of clinical monitoring the European label recommends for patients on ZYPREXA is that which the ADA guidelines denotes as appropriate for any patient with diabetes or risk factors for diabetes regardless of treatment.

Q: Why is this being reported only now?

A: The UK regulatory group (MCA, or Medicines Control Agency) typically communicates routine updates in label changes via their quarterly publication “Current Problems in Pharmacovigilance.” Though it took place in 12/00, the most recent change to the ZYPREXA label in Europe was reported in the April 2002 newsletter, which began to appear this week.

Q: Is this related to the recent ZYPREXA label change in Japan?

A: Information from the recent Japan label change could not have impacted any of the label changes in Europe as these changes in Europe took place in prior to 2001. It is unknown whether the action in Japan impacted the tone or content of the article in the newsletter, however.

Regulatory body for the European Union (the CPMP) has all of our safety data, as well as that of other products in this class, and routinely reviews it. We are in constant communication and will continue to update the agency as needed.

Q: Will we receive copies of the UK report and/or the Reuters and Bloomberg articles?

A: Due to copyright restrictions, we are NOT able to post copies of any of these materials.

A Final Note . . .

We will continue to provide you with updated and timely resources to passionately deliver the ZYPREXA message and confidently and knowledgeably meet customer needs and concerns. Remember, the Lilly sales force is ranked #1 by psychiatrists because of your professionalism, commitment, passion and patient focus and the unlimited knowledge and resources you provide your customers on a daily basis. YOU are your customers’ best partner in their practices. Thank you for your dedication, and good selling!

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