To: CN=Patrizia Cavazzoni/OU=AM/O=LLY@Lilly; CN=Anthony M Fiola/OU=AM/O=LLY@Lilly; CN=Matthew R Pike/OU=AM/O=LLY@Lilly
Date: 07/01/2002 12:05:43 PM
From: CN=Delores K Hanson/OU=AM/O=LLY
Subject: September Zyprexa event- assessment

Tim asked me to forward this to you.

----- Forwarded by Delores K Hanson/AM/LLY on 07/01/2002 11:05 AM -----

Jacques Mosseri

06/26/2002 10:42 AM

To: Timothy F Parshall/AM/LLY@Lilly
cc:
Subject: September Zyprexa event- assessment

----- Forwarded by Jacques Mosseri/EMA/LLY on 06/26/2002 05:42 PM -----

Zvonko Milicevic

06/26/2002 01:38 PM

To: Eugen Grecu/EMA/LLY@Lilly, Jacques Mosseri/EMA/LLY@Lilly
cc: Istvan Bitter/EMA/LLY@Lilly, Andreas Festa/EMA/LLY@Lilly, Heinrich Klech/EMA/LLY@Lilly, Dragan Majetic/EMA/LLY@Lilly, Daiva Masanauskaite/EMA/LLY@Lilly
Subject: September Zyprexa event- assessment

Guys,
Hi again. Here is a summary of our assessement of risks/opportunities/organisational issues related to the September event.

1) issues still to be resolved:
-clearly, there is no global (corporate) strategy on number of topics that we intend to address in the meeting (source: my repated discussions with Dr Sowell, global physcian who is working on these problems); if I'm wrong, than we need to discuss this
-we need to collect input on what has been done by other teams (global, big affiliates) in order to decrease our risk (the US event was organized

before UK and Japanese reports)
-how to streamline discussion within this mixed audiance /our asumptions is that diabetologists do not know much about olanzapine (and other antipsychotics) and their relation to diabetes, while psychiatrists do not know much about metbaolic diseases/; this is why we want to have 2 intro presentations to somehow help them to become "one" audiance; I would need to know how diabetologists are being chosen by the affiliates in order to avoid outcomes like "the best would be to check BG before Zyprexa (or any other anti-psychotic) start and at follow-ups"; we (extrenal and Lilly speakers) may provide some kind of outline for the audience which direction they should go in their discussion in the begining of the meeting?
-clear objective of the meeting to be defined for external people and the framework of the meeting (working session?, symposium?, safety update type of a meeting?)

2) what we can do (our opportunities) (based on my assessment of materials that I've got from the ABT members and initial input from Andreas, as well as my discussion with people from the global team and big affiliates) is:
-to say that evidence exist that number of atypical anti-psychotics, including zyprexa, are associated with BW gain, BW gain correlates with better therapeutic response (so the benefit/side effect ration is very much acceptable)
-to say that no evidence is provided that zyprexa has direct (negative) impact on insulin sensitivity
-to say that no evidence exist that would indicate that zyprexa has direct (negative) impact on insulin-secreting cells
-to say that no evidence exist that zyprexa could be associated directly with increase risk of ketoacidosis (this relates to the Japanese label)
-to say that no evidence exist that zyprexa has proven direct negative impact on lipid metabolism
-to say that no evidence exist that zyprexa has proven causal relationship with pancreatic inflammation (relates to our label in the US)
-to say that evidence exist indicating that zyprexa is probably not worse (vs most other atypicals, we will focus here predominantly on risperidon) with regard to all above mentioned metabolic complications when comparisons are done in scientifically appropriate way

3) what we cannot do (our risks) is:
-to say that no issue could be associated with zyprexa treated patients becuase, through body weigh increase and enormous increase in food consumption which is definite, proven consequence of the tretament, certain subgroups or individual patients may have increased risk for hypertryglyceridemia which may cause acute inflammation of pancreas (very rare cases), or may provoke ketoacidosis (again, due to dietary mistakes, not because of the drug itself)
-to say that the drug is not associated with somewhat increased risk of diabetes, when, this may be the case due to dietary changes, not due to direct effect of the drug (the data are not clear but indicate this, however, this also applies to risperidon, as I said before)
To make it clear, we will not raise these issue, but may come out of the discussion or even external speakers may mantion these things, and if it happens we can say that none of these effects is directly related to drug action, but to the body weight gain and dietary mistake (freqent problem in diabetology)
Looking forward to your comments/suggestions.
I would also appreciate if can get together on the phone and finalize this asap.
Best regards
Zvonko