

BMJ Plan – Phase 4

Situation

Koro paper out in BMJ in early August "Olanzapine Increases the Risk of Diabetes".

The BMS sponsored paper uses the UK GPR database and found 7 cases for olz and 7 cases for risperidone that could possibly be associated with antipsychotic use. They also looked at the control cases of diabetes that were "background". As a result they attribute a p value to the risk of 0.079 for risp as opposed to 0.001 for olz and 0.9 for newer antipsychotics. Hence they are making a statistical association.

Which Means

Hugh is currently reviewing this but in principle this is a finding in this database and nothing more. The Biswas data reinforces the idea that if anything this is VERY RARE issue, applicable to insignificantly variable levels to all antipsychotics and should not therefore be used to "rank" antipsychotics use.

Hugh has completed review and we have input from Peter A and Europe

- Study is nothing more than hypothesis and it does not NOT show what it claims
- The study contained no controlling for even common risk factors such as race.
- The case numbers of 23 for risperidone and 7 for olanzapine are small numbers
- The objective of the paper has inexplicably changed from the original poster presentation of this data
- This is more marketing than science. It is as credible as us using Cavazzoni would be to demonstrate conclusive proof of the association for risperidone.

Plan

1 – Overall our existing strategy remains the same – ie disease effect + possible association with all anti-psychotics – not just olz.

2 – Reinforcement verbatim has been sent to the fieldforce.

3 – Market data reviewed at Zyprexa Ops meeting, 21/8/02 and following agreed:

- Continue with responsive strategy
 - Brief reps on new incidence data (MW - Conference)
 - Build on objection handling competencies (Empl Dev - Conf)
 - Ensure CRP availability for 1:1 phone enquiries (PA)
 - Continue to monitor market place (MW)
 - Inc HDO team in field correspondence

- Safety tracking fieldwork in 1st & 2nd weeks Sept (results 4th week)
- Agree trigger points for change in strategy (MW/NA)
- Prepare message re *rapid* weight gain (MW/PA)
 - Message cascade: disease effect, treatment effect, weight gain and speed of weight gain
- Gather examples of action where prescribers seen diabetes (MW)

N.B. Market data to be reviewed against trigger points (once confirmed) and strategy reviewed accordingly

3 – Peter Aitken and Hiram Wildgust will continue to liaise with agreed KOLs to discuss the Koro paper and ascertain their views on the study (and send them the diabetes pack – slide set, Lilly medical information letter).

4 - Following a discussion between Peter Aitken and Ted Dinan (Prof Psychiatry in Cork), Ted advised that Lilly should not encourage responses to the Koro paper. Therefore, the 'publication response plan' (~ BMJ phase 3 plan) that was planned will be put on hold. This means, at the current time, Lilly will *not* be sending a response letter to the BMJ and will *not* be encouraging our KOLs to respond.

5 – C&W will continue to monitor media for coverage

6 – Continue to pursue our own diabetes write ups based on Metabolic Advisory Board Meeting output, and aim to publish (independent) output A.S.A.P

7 – Hiram to propose and co-ordinate roundtable discussion meeting on physical health issues (ie diabetes and prolactin) with KOL pharmacists (inc Celia Feetam), Peter Aitken and Prof Larry Ereshefsky (on Lilly diabetes panel in US), and Veronica O'Keene (tbc?). Meeting to take place as mini-meeting at Oct UKPPG meeting aiming to share data with influential pharmacists. (honorarium may be required ~ \$500)

8 – Aim to publish report on above meeting.

Action:

1. Millie - brief to Meredith and C&W – to assess views of KOLs but not pursue them to respond to BMJ article, as originally planned (based on advice from Ted)
2. Hiram - prepare for roundtable meeting (and potential publication)