



off-site meeting

June 25, 2002

ACTION PLAN SUMMMERY

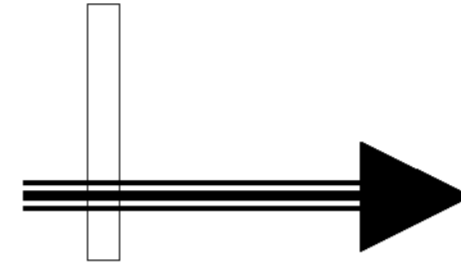
June

July

August

September

Warning, Contraindication,
Precaution



Proper Use (Efficacy +
Safety)

- Field Ride
- OPL Visit
- SMEC-III
- Feedback from Sales
- Issue Management
- Perception Research
- Dr. Fujii Paper

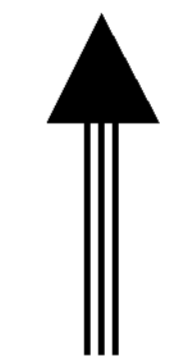


Understanding Safety Use

Mini-MMM



Refined Message
for
Proper Use



Programs

June

July

August

September

Zyprexa
Symposium

WPA

Lilly Speaker
Academy

MATERIALS / TOOLS

Item	(Description)	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Refine Message										
Key Inputs										
Issue Management Study	Global study : Understand physician responses to verbatim around psychotropic use and risk for metabolic complications.		Mid May							
MMM Perception Study	Revise marketing message and identify current physician perceptions around Zyprexa and Lilly since label change.			June 12-15						
Field Communication mtg	Management visit to 5 regions			June 04-10						
Sales force focus group	Internal focus groups with sales reps to assess labeling impact and solicit solution.			Mid June						
Mini-MMM										
Mini-MMM Mtg					July 1st					
Top-lin presentation researches	Issue management and Perception				July 1st					
Discussion for message refine	Mktg, NSTL, 1 sales, PV, MIS				July 1st					
Discussion for targeted patients	Mktg, NSTL, 1 sales, PV, MIS				July 1st					
Develop Brochures draft						2nd and 3rd week of July				
mini-research	mini-research at field					4th week of July				
brochure completion						end July - early Aug				
Key Tools										
Dear Dr. Letter		Apr 16								
Label change related materials	Materials to cope with label change * Diabetes check sheet * Patient explanation sheet * Educational booklet for Diabetes * Q&As etc ...		Label change related materials							
Explanation of Precaution	Deep explanation of Package Insert			Jun 10						
PMS interim report (verbal use)	PMS interim analysis which can use only verbally			Jun 10						
Blood glucose monitoring example (verbal use)	Blood glucose monitoring examples by using PMS interim report			Jun 10						
Confirmation List					end June					
"MARTA"	Periodical "Academic" Newsletter for Drs				Preview	1st issue				2nd issue
Revised Product Monograph	Revision by label change				Start Using TBD					
Refined Message Leaflet	Message for "proper use" Safety and efficacy					Ready				
Case reports (re-start : TBD)							re-start : TBD			
MCS publication								lan to publis		

KEY PROGRAMS

Item	(Description)	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Key Programs										
GMC (3Drs)	We invited 5 Drs but 2 cancelled due to label change issue		GMC (3Drs)							
5 Thought Leaders meeting (May 11)	Discussion on Label Change		May 11							
Luncheon Seminar at JPC	Symposium for Psychosomatologist : 200 joined		May 23							
Web-cast for Luncheon Seminar	On-demand Web-cast of May 23 symposium		May 23							
1yr post Launch Symposium	3 presentations Dr. Tollefson, Dr. Fujii and Dr. Ishigooka : Safety and efficacy \$00 to join				July 06-07					
Satellite Symposium at WPA	400 Drs to join 3 presentations PMS interim report by ELJ and 2 MCS data on Efficacy and safety					Aug 25 or 27				
Lilly Speakers Academy	Peer-to-Peer program Plan to re-invite 1st and 2nd attendees to share new information						Sep 14-15 (TBD)			
Advisory Committee	20 Thought leaders to join							2nd		
JSCNP Luncheon Symposium	200 Drs to join Dr. Fujii is to present safety and efficacy							Oct 04		
Switching Workshop 3	Workshop for fine-tuning of switching method									Mid Dec (TBD)
Key Medical Programs										
PMS (Post Marketing Survey)	3000 cases to be registered									
MCS	50 MCSs : Existing - Efficacy / New - Hyperglycemia									
Special Clinical Study	Decided to be funded in the last JPP						Plan			

PROMOTION

		<u>Messages</u>		<u>Targeted patients</u>		
		safety	proper use ^{Mini - MMM}	DM	Gray Zone (with risk factors)	Safe Zone (w/o risk factors)
Check List	(A) Dr. who well understand about label change	✓	→ ✓	■	■	■
	(B) Dr. who does not understand about label change	✓		■	■	■

- Action Steps -

1. Develop “Check List“ to classify physicians
2. Sales Rep classifies physicians by check list
3. Refine message for proper use via mini-MMM process
4. Refine targeted patients via mini-MMM process also
5. Start promotion for “proper use” to Drs. to be classified as (A)

THOUGHT LEADERS LIST

- Executives -

Thought Leader / Executive List (Zyprexa)					Activities					
Dr. Name	who assigned in Lilly	who will assign	Current position (positive/negative/neutral)	Strategic focus	Apr	May	Jun	Jul	Aug	Sep
K. Kamijima	Taniguchi / Kawasaki	Kawade/Kawasaki	Professor of Showa University	Chairman	Kawasaki(3times) Tonooka Bille	Kawade Tanaka Bille	Taniguchi Kawasaki Tanaka	Kawade Kawasaki	Kawade Kawasaki Tonooka	
M. Murasaki	Taniguchi	Taniguchi/Ishihara	Emeritas Prof. in Kitazato Univ. President of Yutaka Clinic	Chairman	Taniguchi(2times) Ishihara	Taniguchi Bille	Taniguchi	Taniguchi/Ishihara	Taniguchi/Ishihara	
A. Aoba	Kawade	Kawade	Professor of St. Marianna University School of Medicine	Chairman	Kawade(2times) Tanaka Tonooka	Kawade Tonooka	kawade	kawade	kawade	
J. Ishigooka	Taniguchi	Taniguchi	Vice President of Tokiwa Hospital	Presentation	Taniguchi Lakshmanan	Taniguchi Bille	Taniguchi Ishihara	Taniguchi		
S. Kamba	TBD	Bille /Ishihara	Professor of Yamanashi Medical University	R&D	phone (Bille)	Tonooka				
T. Koyama	TBD	Ishihara	Professor of Hokkaido University	Chairman	Ishihara				Tonooka	
M. Sato	Watanabe	Watanabe / Tanaka ?	President of JSPN	Relationship with JSPN		Watanabe Matsumoto	Kawasaki Matsumoto Watanabe	Kawasaki	Tanaka Watanabe	
T. Someya	Taniguchi	Taniguchi	Professor of Niigata University	Relationship with Tokyo Univ		Taniguchi		Taniguchi		
M. Takeda	Kawasaki	Kawasaki	Professor of Osaka Medical University	Chairman	Kawasaki Ishihara		Tanaka			
J. Nakamura	TBD	Matsumoto	Professor of Sangyo Medical University	Chairman		Tanaka				Tanaka
Y. Fujii	Taniguchi	Taniguchi	Vice president of Yamanashi Kita Hospital	Presentation	Taniguchi Matsumoto Ito	Taniguchi kawade Bille Ito	Taniguchi	Taniguchi	Taniguchi	Taniguchi
N. Yamawaki	TBD	Matsumoto	Professor of Hiroshima University	Chairman						
H. Yoneda	TBD	Kawade/Ishihara	Professor of Osaka Medical University	Chairman				Kawade/Ishihara	Kawade/Ishihara	
T. Ohmori	TBD	Matsumoto	Professor of Tokushima University	Presentation				Tonooka		Tonooka
M. Iyo	TBD	Kawasaki	Professor of Chiba university	Presentation						
Y. Nakane	TBD	Matsumoto	Professor of Nagasaki university	Relationship with JSPN		Watanabe		Tanaka	Watanabe	Tanaka
K. Asai	Watanabe	Watanabe / Tanaka ?	Ex-steering member of Nisseikyō	Relationship with MHLW	Watanabe	Watanabe		Tonooka		
Y. Minami	Watanabe / Kawasaki	Ishihara/Watanabe	Important position in Nisseikyō and kaiseikai	Relationship with Nisseikyō / Kaiseikai	Ishihara	Watanabe	Tonooka Watanabe		Watanabe	Tonooka
N. Anzai	TBD	Kawasaki	Manager of Matsuzawa Hp	Presentation						
Y. Sawa	TBD	Kawasaki	President of Sawa Hp	Relationship with Kaiseikai	Kawasaki	Tanaka		Tanaka		

SYMPOSIUM

- **1yr Post-launch symposium (June 06-07)**
 - June 06 : Panel discussion based on questionnaire
 - chairman : Dr. Murasaki
 - Panelists : Dr. Aoba, Fujii, Ishgooka, Tollefson, Nuno (endocrinologist : TBD)
 - June 07 : Presentation
 - Tollefson : “Risk and Benefit of Atypical antipsychotics”
 - Dr. Miyaji / Misawa : “Risk and Benefit based on Blood Glucose Data Analysis of Olanzapine Patients”
 - Dr. Ishigooka : “Risk and Benefit of Blood Glucose Data Analysis of Olanzapine Patients ”
- **WPA ELJ Satellite Symposium (Aug 25 or 27)**
 - PMS Data Analysis :
 - 3 MCS data (Risk and Benefit)
- **Lilly Speakers Academy (Mid Sept : Date TBD)**
 - Re-invite 1st&2nd LSA invitee
 - Updated information and discussion
 - Final plan on discussion with Prof. Kamijima
- **Luncheon Seminar at JSCNP (Oct 04)**

(Japan Society of Clinical NeuroPsychopharmacology)

 - Chairman : Dr. Kamijima
 - Presentation : Dr. Fujii “Comparison of Risk and Benefit between Olanzapine and Risperdal or Haloperidol (TBD)”

LEVERAGE OUR SYNERGY WITH ENDO.

- **Medical Support**

- CRP's support for :

- Developing Materials and tools including an example for Blood glucose monitoring guideline
 - Visiting key institutions for explanation
 - Joining May 11 thought leaders meeting

- **Materials Utilization**

- Utilize educational materials

- Diabetes Treatment Guideline for physicians
 - Diabetes Guideline for co-medicals
 - Educational Materials for patients

- **Endocrinologist Utilization**

- Endo-thought leaders :

- Joined April 5 CNS-ENDO thought leaders meeting
 - To join 1yr post launch symposium

Resolving these issues
will result in rebuilding
trust with the sales force!

REAL ISSUES

Why we are struggling...

• Affecting Company Credibility

- “ELJ did not tell us about Hyperglycemia prior to Dear Dr. Letter...” (Some Drs still think ELJ hide something)
- “ELJ do not let us know why Hyperglycemia happens. Unless we know it, we have to use Zyprexa very carefully.”

• Need concrete guidelines

- Drs. Are asking concrete guideline for key wordings in Dear Dr. Letter
 - “What is During administration of this product, observe sufficiently with such as measurement of blood glucose?”
 - “What is Explain sufficiently to the patient and family members?”
 - “Which patients ELJ recommend to use Zyprexa?”
 - “We know DM patients are contraindication.”
 - “Does ELJ recommend to use Zyprexa to patients with risk factors?”
 - » “Careful administration” is the right answer but it goes back to guideline issue

• Global data does not correlate to label change only for Zyprexa

- Global data always shows no particular difference between atypicals regarding hyperglycemia. It reminds Drs of “Why only Zyprexa only in Japan?” Drs. tend to conclude:
 - Lilly’s data is not neutral. Still hide something
 - Global data is right but ELJ’s aggressive promotion was bad and/or ELJ’s communication with MHLW was not good
 - Japanese patients must be different. Lilly should tell us mechanism to occur Hyperglycemia

• Thought Leaders

- Thought leaders are angry with Lilly due to combination of above.
 - They think Zyprexa is essential. Lilly’s aggressive promotion and bad communication with MHLW must be one reason for Dear Dr. letter.
 - They asked us 1) concrete method of BG monitoring guideline 2) why global data does not correlate to label change? 3) Lilly’s thought on mechanism to be hyperglycemia 4) “neutral position” to deliver Hyperglycemia information 5) Lilly’s thought on patients with risk factors. Our answers are 1) faithful to Dear Dr. letter 2) we do not know 3) we do not know 4) we are neutral 5) careful administration. All answers does not satisfy thought leaders

1. Do not administer to patients with diabetes mellitus and those who have a history of diabetes mellitus.

- In patients with diabetes mellitus and those who have a history of diabetes mellitus, blood glucose may increase and metabolic status may be deteriorated acutely, thus do not administer this product to these patients.

2. During administration of this product, observe sufficiently with such as measurement of blood glucose.

- With the administration of this product, from marked increase in blood glucose, serious adverse reactions such as diabetic ketoacidosis, diabetic coma etc. may appear leading potentially to death. Thus, observe sufficiently with such as measurement of blood glucose during administration of this product.

3. Explain sufficiently to the patient and family members.

- Upon administration of this product, explain sufficiently to the patient and family members possible occurrence of serious adverse reactions, such as diabetic ketoacidosis and diabetic coma etc. Provide guidance to them to see a physician suspending administration if such symptoms as thirst, polydipsia, polyurea or frequent urination etc. appear.

SOLUTIONS ?

- **Affecting Company Credibility**
 - Data disclosure
 - 36 overseas death cases ✓
 - Updated Metabolic Side effects data after Dear Dr. Letter and others as well
 - Good/bad information together
 - All Hyperglycemia data published
 - Hypotheses to occur / not to occur hyperglycemia
- **Need concrete guidelines**
 - Guideline for “observe sufficiently with such as measurement of BG monitoring”
 - We developed one example but it does not satisfy physicians 100%
 - It is an example, not a guideline
 - Patients without risk factors : clinical decision
- **Global data does not correlate to label change only for Zyprexa**
 - Develop domestic data
 - MCS for Hyperglycemia
 - Special Clinical Study decided to be funded by JPP
 - Expose domestic data
 - Fujii’s data / Ishigooka’s data at 1yr post launch symposium
 - PMS interim report at WPA symposium
 - MCS results at WPA symposium
- **“Calm down” thought Leaders**
 - Develop thought leaders management. ✓