

**Unknown**

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**From:** Leong, Ronald  
**Sent:** Friday, December 13, 2002 12:43 PM  
**To:** Beamish, Don G  
**Cc:** Ou, Connie; Warner, Linda (Safety)  
**Subject:** RE: Seroquel Diabetes Japan

**Attachments:** RE: Seroquel Diabetes Japan

Don,

Attached is a table of reports of diabetes and diabetes related adverse events (including DKA, coma), broken down by kind of event, for US, Japan, all other countries. It includes all adverse events, serious and non serious. A second table provides numbers of fatalities among these reports.

To put these reports in proper perspective the following things should be kept in mind:

- 1) These are spontaneous reports from marketed usage. Sometimes the information is incomplete. In many cases the events could be caused by factors such as obesity, diet (drinking large volumes of sugar containing beverages, etc.).
- 2) According to figures we have received, the estimated patient exposure worldwide is approximately 4 million and in Japan 130,000. (I do not have separate figures for the US.)
- 3) Diabetes is common and the prevalence of diabetes in the schizophrenic population is higher than in the general population.

RE: Seroquel  
Diabetes Japan

Our position is that there is insufficient data for a causal relationship between diabetes or glucose dysregulation and Seroquel. We are having a Safety Evaluation Review Meeting Monday, Dec. 16, to review this issue and others, as part of routine processes.

Regards,

Ron Leong

-----Original Message-----

**From:** Beamish, Don G  
**Sent:** Monday, December 09, 2002 5:32 PM  
**To:** Leong, Ronald  
**Subject:** Seroquel Diabetes Japan

Ron,

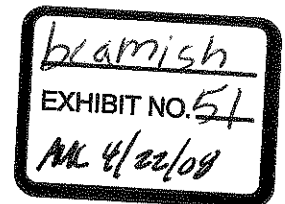
How many cases of SAEs with Seroquel and diabetes including diabetic coma have been reported:

- worldwide
- US
- Japan

How many deaths have been reported in each of the above?

Were you able to find the difference in the incidence of Type I and Type II diabetes between Japan and the US? I know you were looking into this issue based on our earlier meeting.

Thanks



Don