Tamiflu "Wrap-up" and Five Questions for the Committee

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Outline What We Covered

- Tamiflu Regulatory History
- 2005 & 2006 Pediatric Advisory Committee Meetings
- Perspectives from CDC and Japan
- Highlights from the Literature
- Summary of New Data
  - Health Claims data base
  - Preclinical and clinical studies
  - Clinical pharmacology, PK studies

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Earlier PAC Requests Addressed

- Prophylactic use
- Other antiviral products
- Updated FDA safety review: deaths and NP events for Tamiflu and other antivirals using MedDRA terms and narratives
- Drug use data/labeling for Japan/US

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Summary…

FDA continues to receive reports for abnormal behavior in pediatric and adult patients, not fully explained by influenza encephalopathy/encephalitis, but we are unable to definitively determine if it is the drug, the disease or a combination of both.

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Questions to the Panel

1. Based on the totality of data presented today on NP events and the possible relationship to oseltamivir, does the current labeling for oseltamivir adequately address the safety concerns regarding NP events? Yes/No
   a) If no, what other steps should be taken to ensure safe use of oseltamivir in the U.S. (e.g. labeling, risk communication and/or prescriber/patient education)? Please explain.

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Questions to the Panel

2. Based on the totality of the data presented today on NP events and the possible relationship to zanamivir, does the current labeling for zanamivir adequately address the safety concerns regarding NP events? Yes/No
   a) If no, what other steps should be taken to ensure the safe use of zanamivir in the U.S. (e.g. labeling, risk communication and/or prescriber/patient education)? Please explain.

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Questions to the Panel

3. Based on the totality of the data presented today on NP events and the possible relationship to the M2 inhibitors amantadine and rimantadine, does the current labeling for amantadine and rimantadine adequately address the safety concerns regarding NP events? Yes/No
   a) If no, what other steps should be taken to ensure the safe use of amantadine and rimantadine in the U.S. (e.g. labeling, risk communication and/or prescriber/patient education)? Please explain.

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Questions to the Panel

4. Do you have any suggestions for other studies or analyses that are feasible and might clarify this safety issue?
   Please comment.

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Questions to the Panel

5. Presently we meet on a monthly basis during the influenza season to review adverse event reports for the 4 influenza products. We plan to continue the current monitoring schedule. At this time, an update for future PACs is not planned. However, if important safety concerns emerge, we will report back to the committee. Does the committee agree? Yes/No

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