FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee (ALSDAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)

Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Parkway, Gaithersburg, Maryland

October 21-22, 2010

Draft Questions for the Committee

1. Considering the measures and databases currently available, which are likely to be the most effective and efficient metrics and surveillance systems for use in evaluating the impact on abuse and misuse in the community of the introduction of abuse-deterrent opioid formulations?

2. Are new surveillance systems needed in order to evaluate the effect of abuse-deterrent formulations on abuse and misuse? If so, describe what types of systems are needed.

3. Abuse of opioids encompasses several populations at risk including patients, household contacts and individuals unrelated to patients. Abuse of these products may also involve more than one route or method of administration. Discuss how to incorporate these different aspects of abuse and misuse into the evaluation of the effects of the abuse-deterrent formulations.

4. It is unlikely that abuse-deterrent formulations will completely prevent abuse and misuse of opioids. There may be different degrees of change across the measures used to assess abuse and misuse. Can a minimal reduction in abuse and misuse necessary to support a finding of abuse deterrence be determined a priori for these measures?

5. For some drugs, the abuse-deterrent formulations and the non-abuse-deterrent formulations of the same active drug substance will both be on the market at the same time.

    a. In this situation, discuss whether non-abuse-deterrent formulations with the same active drug substance as the abuse-deterrent formulation represent appropriate comparators.

    b. Is there any situation in which it would be considered useful to compare the indicators of abuse and misuse from products with different drug substances?

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Draft Questions for the Committee (Continued)

6. In some instances, the abuse-deterrent formulation will replace the non-abuse-deterrent formulations that were previously marketed.

    a. In this situation, would it be appropriate to limit the evaluation of abuse deterrence to comparisons with the older products?

    b. Would it be necessary or possible to take into account changing patterns in abuse of other drug substances over time?

7. Discuss how a novel analgesic that is introduced to the market in an abuse-deterrent formulation could be evaluated for abuse-deterrent properties?

8. Discuss what constitutes an adequate duration of observation for postmarketing studies of abuse deterrence.

    a. How should market penetration be taken into consideration?

    b. Discuss how sustainability of the effects of an abuse-deterrent product can be assessed over time

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9. The products included to help elucidate the discussion today represent two very different approaches to the development of abuse-deterrent formulations:

    a. physicochemical resistance to manipulation, and

    b. incorporation of an opioid antagonist.

    They also represent two different marketing paradigms:

    c. one in which the original product is removed from the market, and

    d. one in which the original formulation without abuse-deterrent properties will remain on the market at the same time as the product with the abuse- deterrent properties.

    Discuss which aspects of Purdue's proposed studies and King's proposed studies would be potentially useful in the assessment of the abuse-deterrent effects of products, in general, that have been developed to be abuse-deterrent. Please take into consideration the proposed methodologies, outcome measures, study populations, duration of studies and comparators.

    10. Considering your conclusions and recommendations thus far, please discuss which studies, or elements of those studies, would most likely provide consistency in measurement. This is essential in that, as a regulatory body, the Agency must provide a clear and consistent goal for companies requesting a determination of whether or not their product produces a clinically relevant reduction in abuse in the community that would support the inclusion of a claim of abuse-deterrence in the product label.