Overdose Information in Prescription Drug Labeling

Roundtable Agenda | May 14, 2024 | 12:30 – 4:00 PM ET

12:30 pm **Welcome & Introduction**

12:45 pm **Important Overdose Information for Health Care Practitioners**

Lead Reactants & Discussion

- Lead reactants will offer opening remarks to begin discussion about health care practitioner perspectives regarding important overdose information (for example, overdose management information).
- Roundtable participants will have an opportunity to share additional perspectives during the open discussion following lead reactants.

Discussion Questions

1. What overdose information do you consider most useful and likely to impact clinical outcomes?
2. How do healthcare practitioners in various healthcare settings best use overdose information (for example, urgent care center, emergency department, inpatient hospital setting)?

Open Discussion

1:15 pm **Roundtable Discussion | Part 1**

Presentation | Overdose Information in the U.S. Prescribing Information

Moderated Discussion

- All roundtable participants engage in a series of moderated discussions, rotating through key themes and discussion questions.

Discussion Questions

3. Frequently, investigational drugs are tested in clinical studies at a wide range of dosages during development; however, some of these higher tested dosages are not approved. Do you consider specific toxicities that have only occurred in clinical studies at dosages greater than the maximum approved

recommended dosage to be an overdose and should this information be described in the Overdosage section of labeling?

4. When would it be important to describe specific patients that are at higher risk of overdose compared to the general population?
5. When would it be appropriate (or inappropriate) to describe the amount of drug associated with overdose toxicity in the Overdosage section labeling?
6. When would it be appropriate (or inappropriate) to describe drug concentrations associated with overdose toxicity in the Overdosage section labeling?
7. The Overdosage section of labeling regulations state that this section must be based on human data, but if human data are unavailable appropriate animal and in vitro data may be used in this section. If human overdose data is unavailable, what type of animal or in vitro data should be provided in this section?
8. Are there any situations in which the Overdosage section of labeling would clearly be inapplicable (for example, drugs with no or insignificant systemic exposure such as ophthalmic solutions)?

2:30 pm **15-Minute Break**

2:45 pm **Roundtable Discussion | Part 2**

Presentation | Overdose Treatment Information in the U.S. Prescribing Information

Moderated Discussion

- All roundtable participants engage in a series of moderated discussions, rotating through key themes and discussion questions.

Discussion Questions

9. If a drug is associated with overdose, the Overdosage section is required to include specific measures for support of vital functions. What specific measures to treat overdose signs, symptoms, or complications would be helpful to know?
10. Information in drug labeling is focused on the specific information for the subject drug, rather than general practice of medicine information about treating a disease or condition. However, the Overdosage section of labeling regulations are unusual because they require the Overdosage section to include recommended *general* overdose treatment procedures and that such

recommendations be based on data available for the subject drug or experience with pharmacologically related drugs.

a. What recommended *general* overdose treatment information would be helpful for you? For example, should overdose associated with CNS depressants include a recommendation for airway monitoring?

b. What level of evidence available for the subject drug or experience with pharmacologically related drugs is sufficient to include information in the Overdosage section of labeling (for example, clinical studies, mechanistic data, case reports)?

11. Some Overdosage sections of labeling include the following (or similar) statement: "Consider contacting the Poison Help line (1-800-222-1222) or a medical toxicologist for additional overdose management recommendations."

    a. What are your thoughts about including this statement in the Overdosage section of labeling?

    b. When do you think this statement should <u>not</u> be included in the Overdosage section (for example, drugs marketed for a long time that have not been associated with overdose)?

12. Regulations require the Overdosage section of labeling to state whether or not a drug is dialyzable. What additional information would be helpful for you to know about the use of dialysis in the overdose setting?

13. Is there any additional overdose treatment-related information that should be included in the Overdosage section of labeling that has not been discussed? Why?

3:45 pm **Survey Questions**

Zoom Survey

- Participants take time to respond to survey questions via Zoom.

3:55 pm **Closing Remarks**

4:00 pm **Adjournment**

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