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Response to Consumer Healthcare Products Association letter to “Trend in rates of acetaminophen-related adverse events in the United States”

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We thank Sirois for his suggestions on our paper.¹ He raised a concern regarding the use of indirect sales of prescription and over-the-counter (OTC) acetaminophen-containing products in the evaluation of trends in acetaminophen-related adverse event rates in the US population.² In this response, we expand upon the discussion with additional elements to consider in the selection of appropriate data resources.

We agree with Sirois that limitations of the data used in Major *et al.* include the lack of direct point-of-sales to consumers (e.g., sales through outlets such as convenience stores) and the potential for underestimation of actual consumption for OTC products. In the assessment of potential data resources for this project, we considered the relative strengths and limitations of a variety of data resources available to the Agency. One of the attributes considered was the availability of data spanning the 14-year time period examined. While we were able to obtain indirect sales distribution data from 1998 forwards, direct point-of-sales to consumer data obtained from a proprietary data resource were only available from 2007 forwards. The ability to capture data for brand and generic acetaminophen-containing products at the active-ingredient level, including store brand OTC products, was also considered. The OTC store brand product data were not available in the proprietary direct point-of-sales to consumer data resource. In addition, at the time of the analysis, the ability to distinguish between events related to prescription versus OTC acetaminophen-containing products was not available. Changes in methodology and/or data resources, such as focusing on OTC product-related events and/or alternative data resources may yield different utilization-adjusted rates. If comprehensive patient-level utilization data are not available and sales data are considered as a resource for OTC products, we further emphasize the importance of considering these additional data attributes:

1. Inclusion of store brand OTC acetaminophen data such as sales of CVS's, Walgreens's, Target's, and Walmart's brands, as these may account for a large proportion of OTC acetaminophen sales to consumers

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

2. Inclusion of OTC acetaminophen sales data through mass merchandisers and club stores such as Costco and Sam's Club, and other retail outlets such as online sales and kiosks
3. Availability of historical data for analysis of trends across time

In summary, data selection should be made after a careful deliberation of the strengths and limitations of each available resource. In support of our efforts in monitoring the safe use of acetaminophen, we continuously explore different methodologies and data resources to capture the most appropriate measures.

References

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