Health Canada: optimizing transparency and its impact for patients

We are writing in response to the article by Egilman and colleagues published in *CMAJ*, "Optimizing the data available via Health Canada's clinical information portal."[1] Health Canada should be applauded for becoming a world leader in the proactive release of clinical study reports and trial protocols from submissions to support market authorization of drugs and medical devices.[1] However, these valuable documents will have an impact only to the extent that they are used. Given the well-documented biases that pervade the medical literature,[2,3] it is incumbent upon reviewers, developers of clinical practice guidelines, drug formulary decision-makers, educators and others who evaluate drugs and devices to ensure that they utilize clinical study reports and other documents now available through Health Canada.

To further improve transparency, we urge Health Canada to release its reviewer reports on product submissions, showing its interpretations of the data, including any gaps, plans to address these, and the basis for its decisions. The current explanation about data interpretation in the Summary Basis of Decision documents is too brief and inconsistent in terms of how much information is conveyed.[4] As well, we call on Health Canada to establish a framework for releasing de-identified individual patient-level data, as others have done,[5] to allow for full reanalysis and secondary analyses by independent researchers.

The outcome of increased transparency and independent evaluations of drugs and devices will be a more accurate understanding by clinicians of the benefits and harms of our interventions, to the benefit of our patients.

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