ADHD medications and cardiovascular adverse events in children and adolescents: cross-national comparison of risk communication in drug labelling

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Abstract

Purpose
Regulators approve written medical information for healthcare professionals and consumers, but the consistency of these sources has not been studied. We investigated the consistency of information regarding four cardiovascular risks of attention-deficit/hyperactivity disorder (ADHD) medications approved in four countries.

Methods
Professional and consumer product labelling for five ADHD medications approved in Australia, Canada, the UK, and the USA were obtained in March/April 2016. Language describing the relationship between medication and elevated blood pressure and/or heart rate, myocardial infarction, stroke, and sudden death was extracted verbatim and classified into one of four categories based on the described relationship between medication and adverse event: “confirmed,” “unconfirmed,” “mixed,” and “not mentioned.” We judged the consistency of messages delivered to healthcare professionals and consumers as either “consistent” or “inconsistent.”

Results
We obtained 20 healthcare professional labels and 20 corresponding consumer labels for the five ADHD medications registered in all four countries. Not all professional and consumer labelling contained language regarding all four adverse events. Of the 80 theoretically evaluable drug-risk pairs, 38 (48%) were not evaluable because of absence of mention of the adverse event in the consumer label. For the remaining 42, the potential causal relationship was expressed consistently in professional and consumer labelling in 25 (60%) cases. The cardiovascular risk profile was not described consistently across all four countries for any of the five drugs.

Conclusions
Product labelling provides healthcare professionals and consumers with inconsistent messages regarding the potential causal relationship between stimulant use and specific cardiovascular risks in children and adolescents.