

Pages 1, 3-9, 11-51 were removed as the pages contained information that was irrelevant under Section 22 of the FOI Act

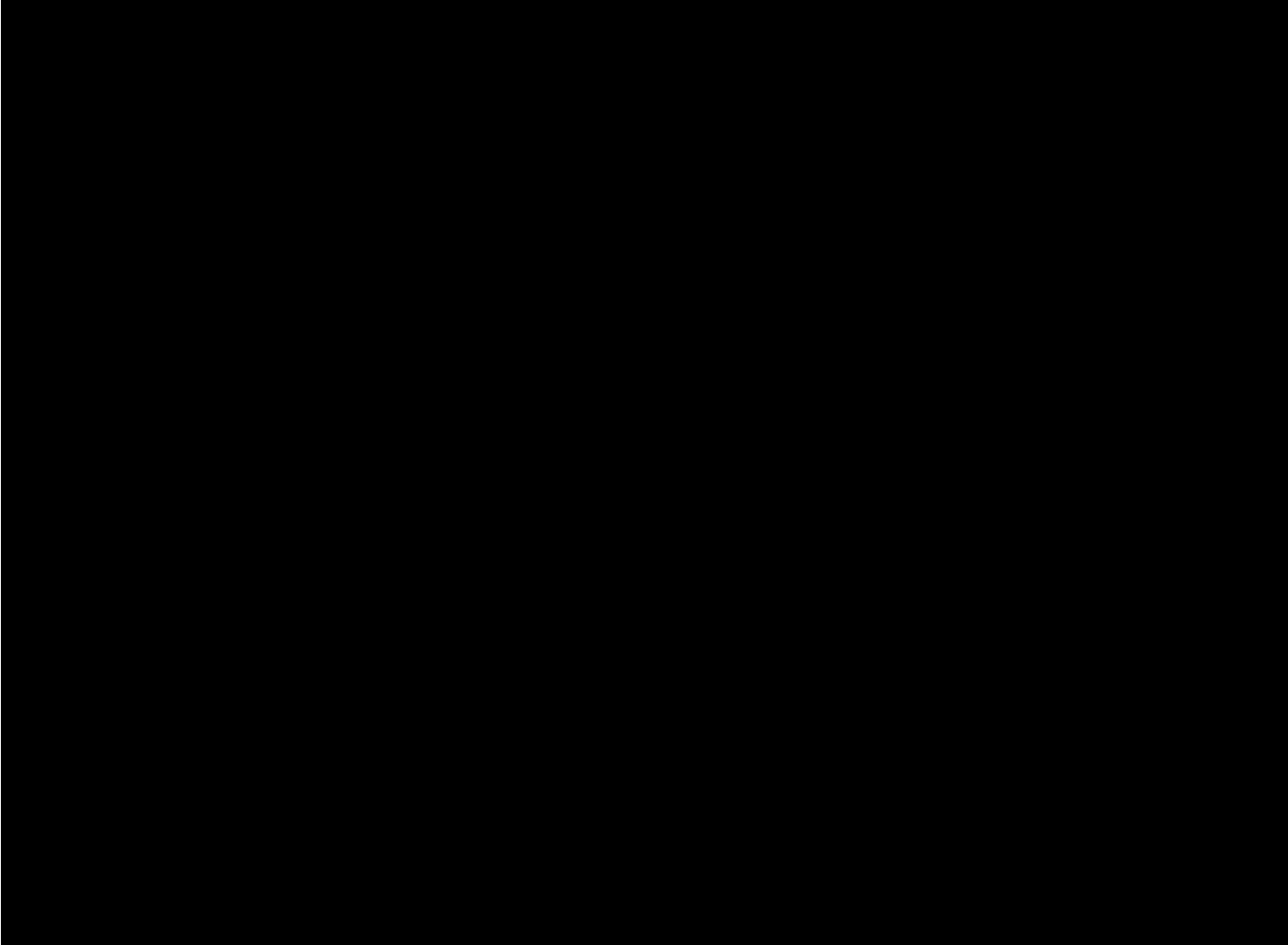
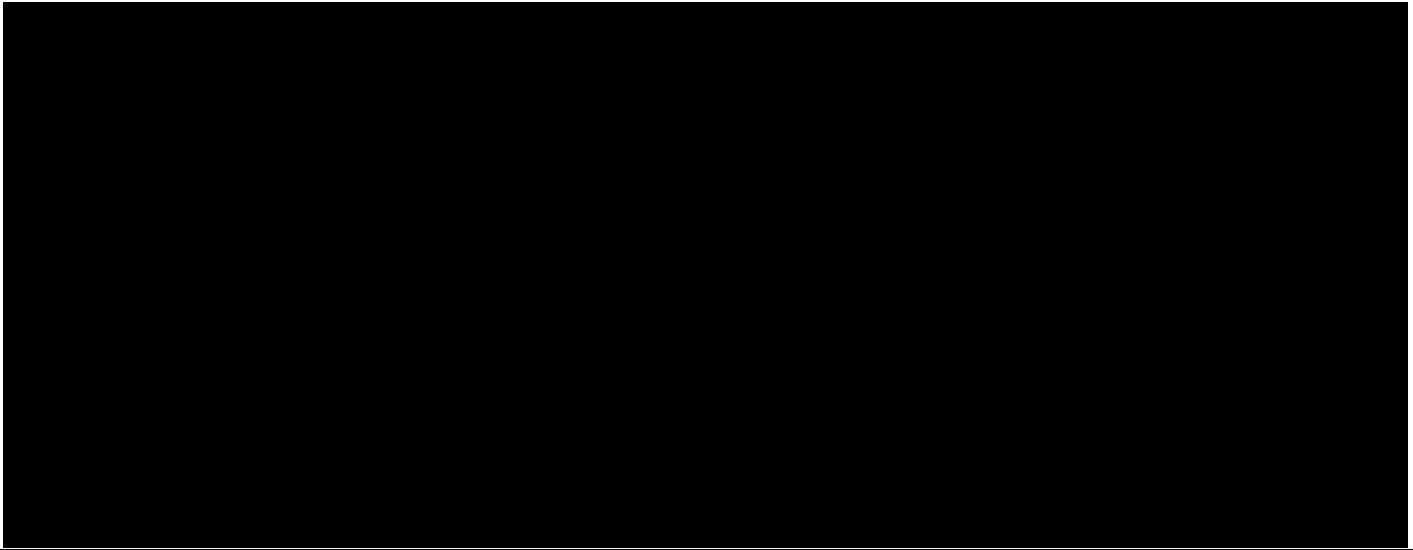
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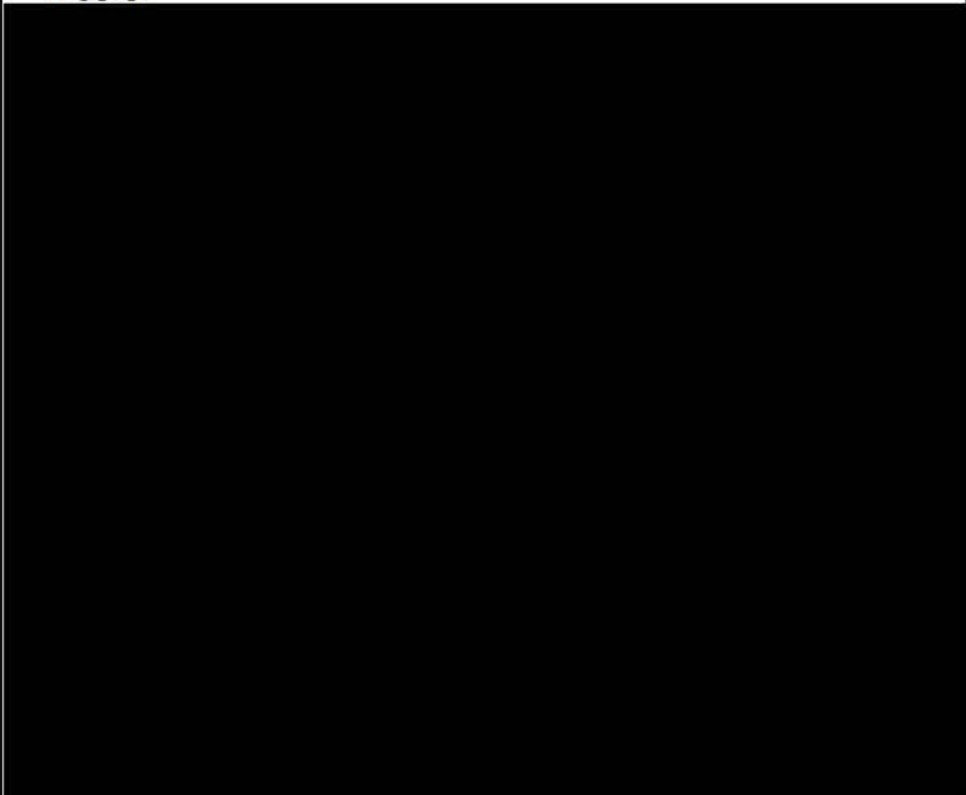

Australia: Commonwealth Department of Health, Therapeutic Goods Administration, Office of Product Review

Canada: Health Canada, Health Products and Food Branch



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10	<p>Restriction of indication for risperidone in dementia to the Alzheimer's type. (HSA)</p> <p>Rationale: In February 2015, Health Canada published a Dear Healthcare Professional Letter regarding the restriction of indication for risperidone in dementia to patients with severe dementia of the Alzheimer type.¹ Other types of dementia such as vascular and mixed types of dementia are no longer indicated. The Canadian product monograph for Risperdal® has been updated to include the new information. This decision was made after a review of information concerning the risks of cerebrovascular adverse events (CVAEs) among patients with dementia treated with anti-psychotics. The risks of such events were found to be higher in among patients with mixed and vascular types dementia compared to those with Alzheimer type dementia.</p>  <p>References</p> <p>1. http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2015/43797a-eng.php</p> 	Written response	HC - 
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