

**TGA Written Response - 4-way pharmacovigilance teleconference**

**May 14/15 2015**

**Topic name: Restriction of indication for risperidone in dementia to the Alzheimer's type**

**TGA Discussion Leader:** [REDACTED]

**Background/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. 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.









