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Proposal for agenda items for the 4-way Pharmacovigilance Teleconference – 14/15 May 2015

Topic:

Restriction of indication for risperidone in dementia to the Alzheimer's type.

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.

