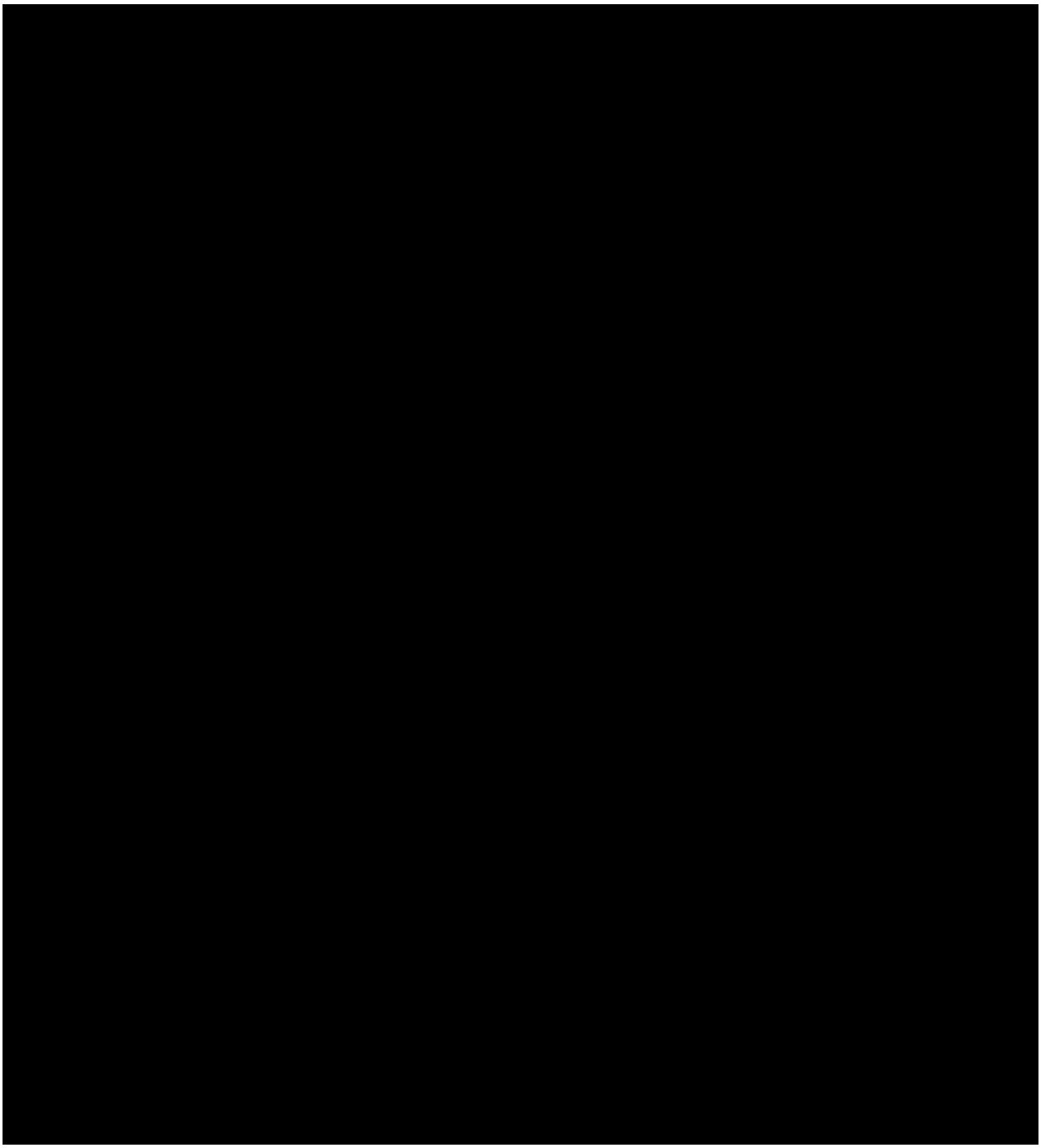
SAFETY FILTER Risperidone and risk of cerebrovascular adverse events in dementia patients (restriction of indication by Health Canada)	PMSB Issue 5998 PMSB Task 7578 TRIM Record R15/392469

1. INTRODUCTION

The TGA received a communication from Health Canada on February 17, 2015 regarding risperidone and Health Canada's intention to restrict the indication to the short-term symptomatic management of aggression or psychotic symptoms in patients with severe dementia of the Alzheimer type, no longer including the treatment of other types of dementia, such as vascular and mixed, due to increased risk of cerebrovascular adverse events in these patients[1]. This information was published on the Health Canada website on February 18, 2015, and was also sent out as part of a Dear Health Professional letter in collaboration with the Canadian sponsor, Janssen Inc.



[redacted]

Health Canada's decision to restrict the indication of risperidone

Prior to this indication update, risperidone was approved for use in severe dementia in Canada. The decision to restrict the indication to use in patients with severe dementia of the Alzheimer type was based on "a comprehensive evaluation of the safety information related to all antipsychotic drugs which indicated a higher risk of cerebrovascular adverse events in patients with the mixed or vascular dementia compared to those with dementia of the Alzheimer type."

[redacted]

The Sponsor also notes previous activity by other regulatory agencies on this issue:

[redacted]

June 2005	Health Canada	Warning about increased mortality rate for elderly patients with dementia-related behaviour disorders treated with atypical antipsychotics.

[redacted]

[redacted]