



Health
Canada

Santé
Canada

Health Products
and Food Branch

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Brian Verbeek
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Dear Mr. Verbeek:

Thank you for your letter of October 24, 2008, addressed to the Minister of Health, enquiring about the status of ADHD (Attention Deficit/Hyperactivity Disorder) as a disease. I am responding on the Minister's behalf.

For mental/psychiatric disorders in general, including depression, anxiety, schizophrenia and ADHD, there are no confirmatory gross, microscopic or chemical abnormalities that have been validated for objective physical diagnosis. Rather, diagnoses of possible mental conditions are described strictly in terms of patterns of symptoms that tend to cluster together; the symptoms can be observed by the clinician or reported by the patient or family members.

Currently, two internationally recognized health professional organizations have published manuals that contain listings of psychiatric disorders and their corresponding diagnostic codes. The two publications are:

- a) the *Diagnostic and Statistical Manual of Mental Disorders (DSM)*, published by the American Psychiatric Association;
- b) the *International Classification of Diseases (ICD)*, published by the World Health Organization.

The primary purpose of these publications, both historically and currently, is to facilitate communication among health professionals on mental disorders, and increase diagnostic agreement. In North America, it is the DSM (version IV-TR) that is relied upon, and in the European Union, it is the ICD (version 10). See website ¹ for Frequently Asked Questions about DSM.

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ADHD as a mental health disorder appears in both references. The drugs approved by Health Canada for this disorder all have the same ADHD indication, including the following:

INDICATION AND CLINICAL USE

DRUG X is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

A diagnosis of ADHD (DSM-IV) implies the presence of hyperactive-impulsive or inattentive symptoms that caused impairment and that were present before age 7 years. The symptoms must be persistent, must be more severe than is typically observed in individuals at a comparable level of development, must cause clinically significant impairment, e.g.: in social, academic, or occupational functioning, and must be present in 2 or more settings, e.g.: school (or work) and at home. The symptoms must not be better accounted for by another mental disorder. For the Inattentive Type, at least 6 of the following symptoms must have persisted for at least 6 months: lack of attention to details/careless mistakes, lack of sustained attention, poor listener, failure to follow through on tasks, poor organization, avoids tasks requiring sustained mental effort, loses things, easily distracted, forgetful. For the Hyperactive-Impulsive Type, at least 6 of the following symptoms must have persisted for at least 6 months: fidgeting/squirming, leaving seat, inappropriate running/climbing, difficulty with quiet activities, "on the go", excessive talking, blurting answers, can't wait turn, intrusive. For a Combined Type diagnosis, both inattentive and hyperactive-impulsive criteria must be met.

Special Diagnostic Considerations

The specific etiology of ADHD is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use not only of medical but of special psychological, educational, and social resources. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation

of the patient and not solely on the presence of the required number of DSM-IV characteristics.

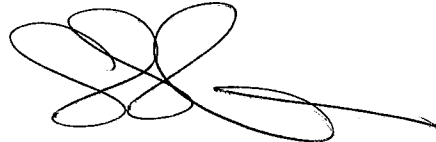
Need for Comprehensive Treatment Program

DRUG X is indicated as an integral part of a total treatment program for ADHD that may include other measures (psychological, educational, social) for patients with this syndrome. Drug treatment may not be indicated for all patients with this syndrome. Drug treatment is not intended for use in the patient who exhibits symptoms secondary to environmental factors and/or other primary psychiatric disorders, including psychosis. Appropriate educational placement is essential in children and adolescents with this diagnosis and psychosocial intervention is often helpful. When remedial measures alone are

insufficient, the decision to prescribe drug treatment medication will depend upon the physician's assessment of the chronicity and severity of the patient's symptoms.

I trust this information to be helpful.

Yours sincerely,

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke extending to the right.

Supriya Sharma, MD MPH FRCPC
Director General