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Canadian Adverse Reaction Newsletter

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www.health.gc.ca/carn

In this issue

Scope

This quarterly publication alerts health professionals to potential signals detected through the review of case reports submitted to Health Canada. It is a useful mechanism to stimulate adverse reaction reporting as well as to disseminate information on suspected adverse reactions to health products occurring in humans before comprehensive risk–benefit evaluations and regulatory decisions are undertaken. The continuous evaluation of health product safety profiles depends on the quality of your reports.

Reporting Adverse Reactions

Canada Vigilance Program
Phone: 866 234-2345
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Second-generation antipsychotics and cardiometabolic adverse reactions in children and adolescents

Key points

- Health Canada received 29 reports of cardiometabolic adverse reactions suspected of being associated with second-generation antipsychotics (SGAs) in children and adolescents under 18 years old.
- In Canada, no SGAs are authorized for use in children or adolescents, with one recent exception authorized for use only in adolescents 15 to 17 years old for the treatment of schizophrenia.
- The cardiometabolic effects of SGAs, which include age-inappropriate weight gain, hypertension, and lipid and glucose abnormalities, have been found to vary by SGA agent.

Excess weight and obesity in the general population are increasing problems throughout the Western world, and this rise has also been observed in children and adolescents.[1] Weight gain and obesity are known to be associated with diabetes, dyslipidemia and hypertension.[2] In addition, weight gain is a well-established adverse reaction (AR) to second-generation antipsychotics (SGAs).[1]

In Canada, there are 7 marketed second-generation antipsychotics: clozapine, risperidone, olanzapine, quetiapine, paliperidone, ziprasidone and aripiprazole. Their date of marketing ranges from 1991 (clozapine) to 2009 (aripiprazole).

Recently, aripiprazole (Abilify) was authorized for the treatment of schizophrenia in adolescents 15 to 17 years old.[3] Previously, there were no authorized indications for the use of SGAs in children or adolescents under 18 years of age in Canada. Pediatric drug use, in many circumstances, has been based primarily on information extrapolated from studies involving adults, as well as from other types of scientific evidence, including case reports, open studies of clinical experience and controlled clinical trials.[4,5] Second-generation antipsychotics have been prescribed for children and adolescents with mental health problems such as schizophrenia, bipolar I disorder, autism, pervasive developmental disorder, disruptive behaviour disorders (including conduct disorder and attention-deficit hyperactivity disorder), developmental disabilities and Tourette syndrome.[6] The use of these drugs in the pediatric population has increased substantially over the last decade.[6–8] According to one estimate, antipsychotic drug prescriptions for children and youth in

Table 1: Summary of 29 reports of cardiometabolic adverse reactions (ARs) suspected of being associated with second-generation antipsychotics in children and adolescents under 18 years of age submitted to Health Canada as of June 30, 2011*

Drug (year of marketing in Canada)	AR; no. of times reported				
	Weight gain	Hyperglycemia or new-onset diabetes	Hypertension	Hyperlipidemia	Total†
Clozapine (1991)	1	0	2	0	3
Risperidone (1993)	5	5	2	2	14
Olanzapine (1996)	9	5	2	1	17
Quetiapine (1997)	2	2	1	0	5

***These data cannot be used to determine the incidence of ARs because ARs are underreported and neither patient exposure nor the amount of time the drug was on the market has been taken into consideration.**
†Some reports may contain one or more reactions and one or more suspected products. Therefore, the total number of ARs does not reflect the total number of case reports.

Canada increased by 114% from 2005 to 2009.[4] Despite this increased use, data regarding their safety are limited.[2]

The cardiometabolic effects of SGAs in pediatric patients, including age-inappropriate weight gain, obesity, hypertension, and lipid and glucose abnormalities, are of concern.[8] Furthermore, children and adolescents with mental health problems often have multiple cardiovascular risk factors, including poor nutrition, inadequate exercise, substance abuse and lack of adequate health care monitoring.[2,9] Some studies have shown that youth using antipsychotic agents may be at a higher risk of weight gain and metabolic effects than adults who use the same drugs.[2,7,10] If weight gain is established in youth, it tends to persist into adulthood.[10]

Because of differences in absorption, distribution and metabolism of antipsychotics in the pediatric population, higher doses per weight are required than in adults to achieve similar efficacy.[2] Cardiometabolic effects are problematic during childhood because they tend to be predictors of adult obesity, metabolic syndrome, hypertension, cardiovascular morbidity and malignant disease.[2,7,8]

Adverse effects such as weight gain have been found to vary significantly by SGA agent. Clozapine and olanzapine seem to be associated with the highest risk of clinically significant weight gain in children and adults.[1,2,7] Risperidone and quetiapine generally show modest risk, whereas ziprasidone and aripiprazole are associated with the lowest risk. Limited data are available for paliperidone.[4] The risk of lipid elevation and increased blood sugar appears to be greatest with olanzapine.[11]

As of June 30, 2011, Health Canada received 29 reports of cardiometabolic ARs in children and adolescents under 18 years suspected of being associated with clozapine (n = 3), risperidone (n = 13), olanzapine (n = 10) and quetiapine (n = 4) (Table 1).* None of the reports implicated paliperidone, ziprasidone or aripiprazole. The case reports included one or more of weight gain, hyperglycemia or new-onset diabetes, hypertension and hyperlipidemia. Of these cases, 21 involved boys and 7 involved girls (sex not specified in one report). The median age of the patients was 14 years. Some reports indicated the use of concomitant medications known to cause weight gain.

There appears to be an increase in off-label use of SGAs in children and adolescents for the management of a number of mental health disorders. The issue of cardiometabolic ARs in children and adolescents taking SGAs has been identified in the literature.[2,4,6,7,11] In addition, the cardiometabolic effects of SGAs have been found to vary by SGA agent. Health Canada encourages the reporting of ARs suspected of being associated with the use of SGAs through the Canada Vigilance Program at www.health.gc.ca/medeffect.

*One of the 29 reports identified 2 SGAs as suspect drugs.

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Prescription drugs and pediatric patients

Key points

- The use of drugs to treat pediatric health conditions is increasing.
- The safety and efficacy of medications may be significantly different in pediatric patients than in adult patients.
- Health Canada recognizes the need to strengthen information related to pediatric health.

In the past, treatment decisions involving the use of drugs in infants, children and youth were often derived from the data in drug studies involving adults.[1,2] However, the safety and efficacy of medications may be significantly different in pediatric patients than in adult patients owing to differences in developmental physiology, disease pathophysiology, and developmental pharmacokinetics and pharmacodynamics.[2] This understanding has led to the use of the phrase "children are not just small adults," a statement that emphasizes the urgent need for evidence from high-quality trials involving pediatric patients.[2]

The use of drugs to treat pediatric health conditions is increasing.[3] Infants, children and youth represent nearly one-quarter of Canada's population and, on average, receive 4 prescriptions a year from a range of more than 1200 different drugs.[3,4] However, data on the efficacy and safety of most medications prescribed for pediatric patients are limited.[2,3,5]

When prescribing a medication for an "off-label" indication in infants, children or youth, health professionals may consult available sources of information, such as peer-reviewed medical literature, pediatric dosing manuals and textbooks, drug formularies at children's hospitals, community pharmacists and the relevant pharmaceutical company representatives. Nonetheless, information provided by these sources may be based more on expert opinion or local practice and experience, in the absence of experimental studies in pediatric populations.[5]

Having stated the above, drug investigations in pediatric populations can be faced with multiple challenges. Some examples include:

- defining appropriate ethical adaptations of clinical trials for studies involving infants, children and youth;[1]
- ensuring adequate sample sizes;[1,2]
- choosing objective, clinically relevant endpoints that can be measured in a valid and reliable manner;[1,2]
- overcoming technical difficulties, such as the need for frequent blood sampling;[1]
- improving pharmacoepidemiologic and pharmacovigilance practices aimed to coordinate the development of reliable information about drug benefits and harms to reduce uncertainties about the use of drugs in pediatric populations; and
- expanding the availability of age-appropriate product formulations (e.g., liquid formulations for younger patients).

Health Canada, like other regulatory authorities around the world, recognizes the need to strengthen information related to pediatric health. In pursuit of this objective, some of its key activities include:

- coordinating the development of pediatric information through the regulatory system and other means;
- coordinating how this information is made available and accessible;
- raising awareness of child health needs and safety issues related to the development and use of health products and food;
- promoting conditions that enable Canadians to make informed decisions about the health and nutrition of infants, children and youth.

To help improve safety data about health products for the pediatric population, it is important for health care providers to continue to report adverse reactions in both pediatric and adult populations to Health Canada (www.health.gc.ca/medeffect).

Marion Haas, Office of Paediatric Initiatives, Health Canada

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Canadian Paediatric Surveillance Program

Since 2004, the Canadian Paediatric Surveillance Program (CPSP), an active surveillance program of the Canadian Paediatric Society, has been collecting reports of serious and life-threatening adverse reactions (ARs), including submissions to the Canada Vigilance Program. The CPSP has been instrumental in building and maintaining a culture of reporting among its members, who number more than 2500 practising pediatricians and pediatric subspecialists. It has simplified the reporting process and increased the likelihood of AR reporting.

Adverse reaction reporting in children: update

In July 2006, the *Canadian Adverse Reaction Newsletter* (*CARN*) communicated the importance of voluntary reporting of potential adverse reactions (ARs) in children to Health Canada.[1] This article provides further details on the type of pediatric AR reports received by Health Canada in 2010. The general overview of AR reporting in 2010 for all ages appeared in the July 2011 issue of *CARN*.[2]

Through the Canada Vigilance Program, Health Canada collects reports of suspected ARs to health products (pharmaceuticals, biotechnology products, blood products and biologics, natural health products, radiopharmaceuticals, and cells, tissues and organs).

In 2010, pediatric AR reports represented 7% of a total of 22 241 cases received; the balance of reports involved adults and elderly people (72%) and people whose age was not reported (21%). Within the pediatric group, the AR distribution by subgroups was 14% for those aged less than 2 years, 44% for those 2 to 11 years and 42% for those 12 to 18 years. Boys accounted for 52% of the reports and girls for 41% (sex not stated in 7%).

The groups of suspect health products most commonly identified in AR reports for each pediatric age subgroup are listed in Tables 1, 2 and 3. Health products are classified by Anatomical Therapeutic Chemical (ATC) groups, according to the World Health Organization's ATC classification system (www.whocc.no/atc_ddd_index/). Several factors may influence the number of ARs reported for a specific health product or product type.[2] In particular, the data reflect the use of health product types within the various age subgroups.

Health Canada continues to monitor the safety profile of marketed health products and communicates, as necessary, new safety information resulting from its post-market surveillance program. Patients and health care professionals are encouraged to report ARs in infants, children and youth through the Canada Vigilance Program (www.hc-sc.gc.ca/dhp-mps/medeff/vigilance-eng.php).[1]

Marielle McMorran, BSc, BSc(Pharm), Health Canada

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Table 1: Top 10 groups of suspect health products most commonly reported in 2010 for children less than 2 years old, by Anatomical Therapeutic Chemical (ATC) group*

Health product (ATC group)	No. (%) of times reported†
Antibacterials for systemic use (J01)	16 (14.6)
Antivirals for systemic use (J05)	14 (12.7)
Immune sera and immunoglobulins (J06)	8 (7.3)
Immunosuppressants (L04)	7 (6.4)
Anti-inflammatory and antirheumatic products (M01)	6 (5.5)
Analgesics (N02)	5 (4.6)
Psychoanaleptics‡ (N06)	5 (4.6)
Antimycobacterials (J04)	4 (3.6)
Antineoplastic agents (L01)	3 (2.7)
Antiepileptics (N03)	3 (2.7)

*Solicited reports or organized data-collection systems (e.g., patient registries, surveys, patient support and disease management programs) may affect the total number of ARs reported for specific products or product types.
†One case may contain one or more suspect products.
‡N06 psychoanaleptics: antidepressants, psychostimulants, psycholeptics and psychoanaleptics in combination, and anti-dementia drugs.

Table 2: Top 10 groups of suspect health products most commonly reported in 2010 for children 2 to 11 years old, by Anatomical Therapeutic Chemical (ATC) group*

Health product (ATC group)	No. (%) of times reported†
Psychoanaleptics‡ (N06)	52 (17.5)
Antineoplastic agents (L01)	30 (10.1)
Antibacterials for systemic use (J01)	26 (8.8)
Corticosteroids for systemic use (H02)	21 (7.1)
Immunosuppressants (L04)	19 (6.4)
Drugs for obstructive airway diseases (R03)	18 (6.1)
Antiepileptics (N03)	15 (5.1)
Anti-inflammatory and antirheumatic products (M01)	13 (4.4)
Anesthetics (N01)	10 (3.4)
Analgesics (N02)	9 (3.0)

*Solicited reports or organized data-collection systems (e.g., patient registries, surveys, patient support and disease management programs) may affect the total number of ARs reported for specific products or product types.
†One case may contain one or more suspect products.
‡N06 psychoanaleptics: antidepressants, psychostimulants, psycholeptics and psychoanaleptics in combination, and anti-dementia drugs.

Table 3: Top 10 groups of suspect health products most commonly reported in 2010 for children 12 to 18 years old, by Anatomical Therapeutic Chemical (ATC) group*

Health product (ATC group)	No. (%) of times reported†
Psychoanaleptics‡ (N06)	69 (20.0)
Immunosuppressants (L04)	60 (17.4)
Sex hormones and modulators of the genital system (G03)	30 (8.7)
Antibacterials for systemic use (J01)	20 (5.8)
Analgesics (N02)	20 (5.8)
Antineoplastic agents (L01)	14 (4.1)
Psycholeptics‡ (N05)	12 (3.5)
Antiepileptics (N03)	9 (2.6)
Anti-acne preparations for topical use (D10)	7 (2.0)
Other nervous system drugs (N07)	6 (1.7)

*Solicited reports or organized data-collection systems (e.g., patient registries, surveys, patient support and disease management programs) may affect the total number of ARs reported for specific products or product types.
†One case may contain one or more suspect products.
‡N05 psycholeptics: antipsychotics, anxiolytics, hypnotics and sedatives; N06 psychoanaleptics: antidepressants, psychostimulants, psycholeptics and psychoanaleptics in combination, and anti-dementia drugs.

Adverse reactions (ARs) to health products are considered to be suspicions, as a definite causal association often cannot be determined.
Spontaneous reports of ARs cannot be used to estimate the incidence of ARs because ARs remain underreported and patient exposure is unknown.

Health Canada Santé Canada

Canada Vigilance Adverse Reaction Reporting Form

Report of suspected adverse reactions to marketed health products in Canada

See instructions and information on adverse reaction reporting and confidentiality at http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php.
Complete all mandatory items, marked by a *, and provide as much information as possible for the remaining items. PROTECTED WHEN COMPLETED – B**

A. Patient Information

1. Identifier

2. Age	3. Sex*	4. Height	5. Weight
☐ Years ☐ Months	☐ Male ☐ Female	_____ cm _____ feet	_____ kg _____ lbs

B. Adverse Reaction

1. Outcome attributed to adverse reaction (Select all that apply)

- ☐ Death: (yyyy-mm-dd)
- ☐ Life-threatening
- ☐ Hospitalization
- ☐ Hospitalization – prolonged
- ☐ Disability
- ☐ Congenital malformation
- ☐ Required intervention to prevent damage/impairment
- ☐ Other:

2. Reaction date (yyyy-mm-dd)

3. Report date (yyyy-mm-dd)

4. Describe reaction or problem*

5. Relevant tests/laboratory data (including dates (yyyy-mm-dd))

6. Relevant history and pre-existing medical conditions
(e.g. allergies, pregnancy, smoking/alcohol use, hepatic/renal dysfunction)

C. Suspected Health Product(s)

1. Name*, strength and manufacturer (if known)

#1

#2

2. Dose, frequency and route used

#1 | #2

3. Therapy dates (or duration)

#1 From (yyyy-mm-dd) - To (yyyy-mm-dd) | #2 From (yyyy-mm-dd) - To (yyyy-mm-dd)

4. Indication for use

#1 | #2

5. Reaction abated after use stopped or dose reduced

#1 ☐ Yes ☐ No ☐ Does not apply | #2 ☐ Yes ☐ No ☐ Does not apply

6. Lot #

#1

#2

7. Expiration

#1 (yyyy-mm-dd)

#2 (yyyy-mm-dd)

8. Reaction reappeared after reintroduction

#1 ☐ Yes ☐ No ☐ Does not apply | #2 ☐ Yes ☐ No ☐ Does not apply

9. Concomitant health products, excluding treatment of reaction
(name, dose, frequency, route used and therapy dates (yyyy-mm-dd))

10. Treatment of reaction, including dates (yyyy-mm-dd)

D. Reporter Information

1. Name*, occupation, address, telephone number*

2. Health professional?	3. Reported to manufacturer?
☐ Yes ☐ No	☐ Yes ☐ No

** As per the Treasury Board of Canada Secretariat Government Security Policy.

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Canada

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Spontaneous reports of ARs cannot be used to estimate the incidence of ARs because ARs remain underreported and patient exposure is unknown.

Did you know? DSEN and pediatric projects

The Drug Safety and Effectiveness Network (DSEN) was established by the Canadian Institutes of Health Research in partnership with Health Canada and in collaboration with stakeholders from across Canada.

The key objectives for DSEN are:

- to increase the evidence on drug safety and effectiveness available to regulators, policy-makers, health care providers and patients; and
- to increase capacity within Canada to undertake high-quality post-market research in the area of drug safety and effectiveness.

One of the several funded pediatric projects aims to study pediatric prescribing rates of second-generation antipsychotics (SGAs). The objective is to develop a standardized procedure for the safe monitoring of these medications in children and youth. More information is available at http://webapps.cihr-irsc.gc.ca/cfdd/db_search?p_language=E&p_competition=200910DSA

Quarterly summary of health professional and consumer advisories

(posted on Health Canada's Web site: Aug. 23, 2011 – Nov. 22, 2011)

Date*	Product	Subject
Nov 16	CooperVision contact lenses	Recall: presence of a residue on lenses for certain lots
Nov 9 & 14	Avastin (bevacizumab)	Higher incidence of ovarian failure in premenopausal women
Nov 7	Fluoroquinolone antibiotics	Risk of increased muscle weakness for patients with myasthenia gravis
Nov 3 & 8	Pradax (dabigatran) and Plavix (clopidogrel)	Brand name confusion
Nov 2	Colgate Motion Electric Toothbrush	Recall: reports of toothbrush exploding
Oct 25 & 28	Xigris (drotrecogin alfa)	Product withdrawal
Oct 25	Brewer's Yeast tablets	Recall: presence of an undeclared milk allergen
Oct 21 & 24	Strattera (atomoxetine)	Association with increased blood pressure and increased heart rate
Oct 13	Citalopram	Review of dose-related heart risk
Sept 22	Plavix (clopidogrel)	New recommendations for use with proton-pump inhibitors
Sept 19 & 21	Trasylol (aprotinin)	Important new safety information
Sept 12	HIV home test kits	Unlicensed products
Sept 8	Gonadotropin-releasing hormone agonists	Heart-related risk in men treated for prostate cancer
Sept 1	Bi Yan Pian	Recall: excessive amount of mercury
Aug 29	Donor semen	Reminder of potential dangers of using donor semen from questionable sources
Aug 26 & 30	Sprycel (dasatinib)	Reports of pulmonary arterial hypertension
Aug 22	Central vascular access devices	Complications of catheter pinch-off
Aug 15	Uromitexan (mesna)	Association of the multi-dose vials with fatal gasping syndrome in neonates and infants
July 5	SynchroMed II implantable drug-infusion pumps	Update on battery performance of model 8637
Aug 23 to Nov 22	Foreign products	12 Foreign Product Alerts (FPAs) were posted on the Health Canada Web site during this period; FPAs are available online (www.hc-sc.gc.ca/ahc-asc/media/index-eng.php) or upon request

Advisories are available at www.health.gc.ca/medeffect.
*Date of issuance. This date may differ from the posting date on Health Canada's Web site.

Canadian Adverse Reaction Newsletter

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Suggestions?

Your comments are important to us. Let us know what you think by reaching us at mhpd_dpsc@hc-sc.gc.ca

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