Children-Adolescents:

15 suicides reported to FDA 2004-2006

(Strattera reported as Primary Suspect Drug)

9	Years	M	6079094
10	Years	M	5983572
12	Years	M	6030367
14	Years	M	5913951
14	Years	M	6183286
15	Years	M	5671703
15	Years	M	5952177
16	Years	M	5951902
16	Years	M	5952177
17	Years	M	4152711
17	Years	M	5738728
17	Years	M	5903501
18	Years	M	4168987
18	Years	M	6026869
19	Years	F	5923694

+1 additional suicide (13 years) in Annex 4 (Risk Benefit Assessment, January 2006, Cumulative review 02-05)

"Case ' *(completed suicide)* was initially reported by a funeral home director with additional information from the medical examiner and a consumer, concerns a 13-year-old Caucasian male patient with an unknown medical history. He was not receiving any concomitant Medications"

+2 cardiac death in FDA 2004-2006,

6	Years	M	5876785
8	Years	M	4199197

+3 additional in Risk-Benefit Assessment (p. 35)

"During the period 26 November 2002 – 30 September 2005 there were a total of 11 case reports of cardiac disorders with a fatal outcome. **These fatal cases involved 5 children and adolescents** and 6 adults."

+2 other children in FDA 2004-2006

5	Years	M	5882337
10	Years	M	6109466

+4 small children under 6 mentioned in PSUR 9 (cumulative)

There were 72 adverse events that were considered as serious and included in 48 serious case reports, **4 of which resulted in a fatal outcome. One fatal case was a hearsay case with no detailed information, involving a 3-year-old female who died of an unknown cause. The second case involved a patient who died of drowning. The third case involved a 2-year-old who was taking both atomoxetine and olanzapine at high doses at the time of her death. The forth concerned a 5-year-old male who died during a school activity, possibly due to an asthma attack.** Though the HCP reporters in the last 2 fatal cases commented that the events were unlikely associated to atomoxetine, based on the information provided, the role of atomoxetine in these 2 cases could be neither confIrmed nor ruled out.

Summary: 15+1+11= 27 children and adolescents reported dead in FDA 2004-2006 and in PSURs

Adults:

13 suicides reported to FDA 2004-2006

20	Years	F	5796217
21	Years	M	6054812
21	Years	M	6157560
27	Years	M	5899462
28	Years	M	6183275
35	Years	F	4101722
35	Years	M	4141401
39	Years	M	5744981
		F	5892273
		M	5897087
		M	5919125
		M	5939430
		M	6168850

+ 4 suicides in Annex 4 (Cumulative review 2002-2005)

"Case *(intentional misuse, completed suicide),* reported by a psychiatrist, concerned a 42-year-old male patient with a history of ADD, depression, hypothyroidism and back pain.
Case *(death, vomiting),* reported by a physician, with additional information from a nurse, concerned a 32-year-old black female patient.
Case *(drug toxicity, abnormal behaviour, excoriation),* reported by a medical examiner, concerned a 47-year-old Caucasian female patient weighing 72 kg.
Case ' *(death, drug level increased)* reported by a psychiatrist, concerned a 41-year-old female African American patient..."

+4 suicides in PSUR 9 (May 2007-November 2007)

Case *(completed suicide)* concems with medical history including borderline personality disorder, later diagnosed as ADHD.
Case *(completed suicide)* concerns with a medical history including the use of different unspecified stimulants and concomitant medications were not provided.
Case *(completed suicide)* concerns receiving atomoxetine, dose unknown, for an unspecified indication beginning on an unknown date.
Case *(completed Suicide)* concerns whose medical history and concomitant medications were not provided.

+4 adults/stillbirth in FDA 2004-2006

46	Years	M	6046261
51	Years	M	6018744
	Stillbirth		6041125
	Stillbirth		6045434

+2 cardiac death/sudden death in FDA 2004-2006

45	Years	F	4148360
65	Years	F	5862506

+4 additional in Risk-Benefit Assessment (p. 35)

"During the period 26 November 2002 – 30 September 2005 there were a total of 11 case reports of cardiac disorders with a fatal outcome. These fatal cases involved 5 children and adolescents and **6 adults."**

Summary: 21+10= 31 adults

SUMMARY FROM FDA 2004-2006 AND PSURs:
27 children and adolescents + 31 adults = 58 deaths

Below are reports about deaths from Strattera treament, reported from January 13, 2006 – September 04, 2007.

(From what can be seen they are not duplicate reports of what is described above. However doublereporting cannot be ruled out in some cases; something the MHRA will find out when gaining access to the original reports.)

Source Patientsville:

http://patientsville.com/medication/strattera10_side_effects.htm

STRATTERA problem was reported by a Physician from UNITED STATES on Jan 13, 2006. Male patient, 71 years of age, weighting 168.9 lb, was diagnosed with attention deficit/hyperactivity disorder, erectile dysfunction and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **acute myocardial infarction, cardiac arrest, loss of consciousness, ventricular fibrillation**. STRATTERA dosage: unknown. During the same period patient was treated with **CIALIS, LIPITOR, ATENOLOL, IMDUR, PRILOSEC, LISINOPRIL**. Patient died on 01/04/2005.

STRATTERA problem was reported by a Physician from NETHERLANDS on Jan 25, 2006. Male patient, 30 years of age, was diagnosed with abnormal behaviour and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **depression, indifference, injury asphyxiation, intentional self-injury, suicidal ideation**. STRATTERA dosage: 80 MG, ORAL. During the same period patient was treated with **CISORDINOL, DIPIPERON**. Patient died.

STRATTERA problem was reported by a Physician from UNITED STATES on Feb 07, 2006. Female patient, 27 years of age, was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **back pain, circulatory collapse, convulsion, dizziness, euphoric mood, fall, lung infiltration, neck pain, pyrexia**. STRATTERA dosage: 40 MG, DAILY (1/D),. During the same period patient was treated with **ATENOLOL, DOXAZOSIN, LISINOPRIL, FLUOXETINE, DEPAKOTE, METFORMIN, HYDROCORTISONE, FLUDROCORTISONE ACETATE**. Patient died on 01/11/2006.

Consumer or non-health professional from ROMANIA reported STRATTERA problem on Feb 06, 2006. Female patient, **17 years of age**, was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **blood glucose increased, dizziness, hyperaemia, intentional overdose, nausea**. STRATTERA dosage: 560 MG, OTHER, ORAL. Patient was **hospitalized**. Patient died.

STRATTERA problem was reported by a Consumer or non-health professional from UNITED STATES on Feb 21, 2006. Female patient, 53 years of age, weighting 165.3 lb, was diagnosed with attention deficit/hyperactivity disorder, depression and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **intentional self-injury, prescribed overdose, stress, suicidal ideation**. STRATTERA dosage: 180 MG, DAILY (1/D). During the same period patient was treated with **CYMBALTA, TOPAMAX, GEODON, PROVIGIL, RITALIN, EFFEXOR, ATIVAN**. Patient died.

Consumer or non-health professional from UNITED STATES reported STRATTERA problem on Feb 21, 2006. Male patient, 24 years of age, weighting 179.9 lb, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **arrhythmia, cardiomegaly, hypertrophic cardiomyopathy, pulmonary congestion, pulmonary oedema, ventricular hypertrophy, vomiting**. STRATTERA dosage: 20 MG, 2/D,. Patient died.

STRATTERA problem was reported by a Consumer or non-health professional from UNITED STATES on Feb 21, 2006. Female patient, **child 11 years of age**, weighting 117.9 lb, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **arrhythmogenic right ventricular dysplasia, attention deficit/hyperactivity disorder, cardiac failure, circulatory collapse, dilatation ventricular, loss of**

consciousness, malaise, mydriasis, pericardial effusion. STRATTERA dosage: unknown. During the same period patient was treated with **ADDERALL**. Patient died.

STRATTERA problem was reported by a Physician from GERMANY on Feb 28, 2006. Male patient, **child 9 years of age**, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. STRATTERA dosage: 25 MG, DAILY (1/D), ORAL. Patient was **hospitalized**. Patient died.

STRATTERA problem was reported by a Physician from UNITED STATES on Apr 03, 2006. Female patient, 31 years of age, was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **intentional overdose, tachycardia**. STRATTERA dosage: unknown. During the same period patient was treated with **RITALIN, ZOLOFT**. Patient was **hospitalized**. Patient died.

Health Professional from UNITED STATES reported STRATTERA problem on Mar 27, 2006. Female patient, **17 years of age**, was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **family stress, mydriasis, partner stress, tachycardia, vomiting**. STRATTERA dosage: 40 MG. During the same period patient was treated with **EFFEXOR, LAMICTAL**. Patient was **hospitalized**. Patient died. (Health Professional from UNITED STATES reported STRATTERA problem on May 09, 2006. Female patient, 17 years of age, was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **hepatic enzyme increased, intentional overdose, mydriasis, tachycardia, vomiting**. STRATTERA dosage: 800 MG,. During the same period patient was treated with **EFFEXOR, LAMICTAL**. Patient was **hospitalized**. Patient died.?)

Physician from GERMANY reported STRATTERA problem on Mar 30, 2006. Male patient, **16 years of age**, weighting 149.9 lb, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **depression, injury asphyxiation**. STRATTERA dosage: 40 MG, DAILY (1/D), ORAL : 60 MG, DAILY (1/D), ORAL. During the same period patient was treated with **CONCERTA, DIPIPERON**. Patient died

STRATTERA problem was reported by a Physician from UNITED STATES on Apr 06, 2006. Female patient, **child 12 years of age**, was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **nervous system disorder**. STRATTERA dosage: unknown. Patient died.

STRATTERA problem was reported by a Physician from MEXICO on Apr 04, 2006. Male patient, **16 years of age**, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **coordination abnormal, feeling drunk, intentional self-injury, pyromania, weight increased**. STRATTERA dosage: 40 MG, 2/D, ORAL. During the same period patient was treated with **OLANZAPINE, MIRTAZAPINE**. Patient was **hospitalized**. Patient died.

STRATTERA problem was reported by a Physician from UNITED KINGDOM on Apr 12, 2006. Male patient, **child 11 years of age**, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **intentional self-injury**. STRATTERA dosage: 50 MG. During the same period patient was treated with **METHYLPHENIDATE**. Patient died.

Physician from GERMANY reported STRATTERA problem on May 03, 2006. Female patient, **13 years of age**, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **educational problem, frustration, self esteem decreased, skin laceration**. STRATTERA dosage: 40 MG, DAILY (1/D), ORAL. During the same period patient was treated with **MEDIKINET**. Patient died.

STRATTERA problem was reported by a Physician from GERMANY on May 04, 2006. Female patient, 20 years of age, weighting 141.1 lb, was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **agitation, alcohol use**. STRATTERA dosage: 600 MG, OTHER, ORAL. During the same period patient was treated with **ALCOHOL**. Patient died.

Physician from UNITED STATES reported STRATTERA problem on May 24, 2006. Male patient, **13 years of age**, weighting 112.4 lb, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **bipolar disorder, injury asphyxiation, suicidal ideation**. STRATTERA dosage: 60 MG DAILY (1/D). During the same period patient was treated with **LEXAPRO**. Patient was **hospitalized**. Patient died.

STRATTERA problem was reported by a Physician from UNITED STATES on May 30, 2006. Male patient, **child 8 years of age**, was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **suicidal ideation**. STRATTERA dosage: unknown. Patient died.

STRATTERA problem was reported by a Consumer or non-health professional from UNITED STATES on June 14, 2006. Male patient, 33 years of age, was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **anaphylactic reaction, hypotension**. STRATTERA dosage: unknown. Patient died.

Physician from CANADA reported STRATTERA problem on June 12, 2006. Male patient, 49 years of age, weighting 149.9 lb, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **loss of consciousness, myocardial infarction, prescribed overdose**. STRATTERA dosage: unknown. During the same period patient was treated with **ALCOHOL**. Patient died on 07/06/2005.

Physician from MEXICO reported STRATTERA problem on June 29, 2006. Female patient, **14 years of age**, weighting 121.3 lb, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **anxiety, intentional self-injury, mental status changes**. STRATTERA dosage: 60 MG, DAILY (1/D) ORAL. Patient died.

STRATTERA problem was reported by a Physician from NORWAY on July 07, 2006. Male patient, 35 years of age, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **overdose**. STRATTERA dosage: 80 MG, DAILY (1/D); ORAL. During the same period patient was treated with **BENZODIAZEPINE DERIVATIVES**. Patient died.

STRATTERA problem was reported by a Physician from GERMANY on July 18, 2006. Female patient, **16 years of age**, was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **intentional overdose, vomiting**. STRATTERA dosage: 250 MG, OTHER, ORAL : 240 MG, OTHER,ORAL. Patient was **hospitalized**. Patient died.

STRATTERA problem was reported by a Physician from MEXICO on July 20, 2006. Male patient, **child 5 years of age**, was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **cardiac disorder, heart rate increased**. STRATTERA dosage: unknown. Patient died.

STRATTERA problem was reported by a Physician from NETHERLANDS on July 27, 2006. Male patient, **13 years of age**, weighting 86.86 lb, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **convulsion, drowning, grand mal convulsion**. STRATTERA dosage: unknown. During the same period patient was treated with **DEPAKENE, TEGRETOL, RIVOTRIL**. Patient died on 07/26/2006.

STRATTERA problem was reported by a Physician from GERMANY on July 27, 2006. Female patient, **15 years of age**, weighting 110.2 lb, was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **intentional overdose**. STRATTERA dosage: 120 MG. Patient was **hospitalized**. Patient died.

STRATTERA problem was reported by a Physician from VENEZUELA on Aug 21, 2006. Male patient, **child 10 years of age**, weighting 77.16 lb, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **family stress, injury asphyxiation, intentional self-injury, neck injury, thermal burn**. STRATTERA dosage: 18 MG, DAILY (1/D), ORAL. During the same period patient was treated with **VITAMINS NOS**. Patient died.

STRATTERA problem was reported by a Consumer or non-health professional from UNITED STATES on Jan 22, 2007. Female patient, 28 years of age, weighting 110.0 lb, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **coma, incorrect dose administered**. STRATTERA dosage: 80MGS ONCE DAILY PO. Patient was **hospitalized**. Patient died.

Physician from GERMANY reported STRATTERA problem on Jan 11, 2007. Male patient, **child 11 years of age**, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **aggression, physical assault, self injurious behaviour**. STRATTERA dosage: unknown. Patient died.

STRATTERA problem was reported by a Physician from UNITED STATES on Feb 02, 2007. Female patient, 50 years of age, weighting 154.0 lb, was diagnosed with depression and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **gallbladder disorder**.

STRATTERA dosage: 40 MG, 2/D. During the same period patient was treated with **WELLBUTRIN, NORTRIPTYLINE**. Patient died on 05/10/2006.

STRATTERA problem was reported by a Physician from CANADA on Jan 29, 2007. Male patient, **14 years of age**, was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **suicidal ideation**. STRATTERA dosage: 18 MG, UNK. During the same period patient was treated with **RIVOTRIL, WELLBUTRIN, EFFEXOR**. Patient died.

Physician from PUERTO RICO reported STRATTERA problem on Jan 30, 2007. Male patient, **child 9 years of age**, weighting 74.99 lb, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. STRATTERA dosage: 18 MG, UNK. Patient died on 12/01/2005.

STRATTERA problem was reported by a Pharmacist from UNITED STATES on Feb 16, 2007. Female patient, **14 years of age**, weighting 117.9 lb, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **abnormal behaviour, depressed level of consciousness, family stress, incorrect dose administered, sleep disorder**. STRATTERA dosage: 80MG DAILY PO. During the same period patient was treated with **SEASONALE**. Patient was **hospitalized**. Patient died.

Physician from GERMANY reported STRATTERA problem on Feb 08, 2007. Male patient, 25 years of age, weighting 165.3 lb, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **intentional overdose**. STRATTERA dosage: 960 MG, UNK. During the same period patient was treated with **PIPAMPERONE**. Patient was **hospitalized**. Patient died.

Pharmacist from UNITED STATES reported STRATTERA problem on Feb 20, 2007. Male patient, **weighting 80.25 lb,** was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **suicidal ideation**. STRATTERA dosage: 25 MG ONCE DAILY PO. Patient was **hospitalized**. Patient died.

STRATTERA problem was reported by a Physician from CHILE on Feb 15, 2007. Male patient, **17 years of age,** was diagnosed with attention deficit/hyperactivity disorder, personality disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **extrapyramidal disorder, intentional overdose**. STRATTERA dosage: 800 MG, DAILY (1/D). During the same period patient was treated with **VALPROIC ACID, VALPROIC ACID, SPIRON, SOCIAN, RAVOTRIL, PAROXETINE**. Patient was **hospitalized**. Patient died.

STRATTERA problem was reported by a Physician from UNITED STATES on Feb 20, 2007. Male patient, **15 years of age**, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. STRATTERA dosage: 80 MG, UNK. Patient was **hospitalized**. Patient died.

Physician from GERMANY reported STRATTERA problem on **July 10, 2007. Male patient, 15 years of age**, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. STRATTERA dosage: unknown. During the same period patient was treated with **ALCOHOL**. Patient was **hospitalized**. Patient died.

STRATTERA problem was reported by a Consumer or non-health professional from UNITED STATES on July 23, 2007. Female patient, 33 years of age, weighting 150.0 lb, was diagnosed with bipolar disorder and was treated with STRATTERA. STRATTERA dosage: MAY 1, 2007 60 MG QD PO MAY 16, 2007 80 MG QD PO. During the same period patient was treated with **ZOLOFT, LEXAPROL, CELEXA, ABILIFY, GEODON, WELLBUTRIN, LAMICTAL**. Patient died on 06/25/2007.

Physician from UNITED STATES reported STRATTERA problem on July 13, 2007. Male patient, 42 years of age, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **sleep disorder, somnolence**. STRATTERA dosage: 40 MG, DAILY (1/D). During the same period patient was treated with **CLONOPIN**. Patient died.

Consumer or non-health professional from UNITED STATES reported STRATTERA problem on July 17, 2007. Male patient, **child 12 years of age**, was treated with STRATTERA. STRATTERA dosage: unknown. Patient died

Physician from UNITED STATES reported STRATTERA problem on **Aug 15, 2007. Male patient, 16 years of age**, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. STRATTERA dosage: unknown. Patient died on 01/01/2007.

Consumer or non-health professional from UNITED STATES reported STRATTERA problem on Sept 04, 2007. Female patient, 36 years of age, was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: coma, **intentional overdose**. STRATTERA dosage: unknown. During the same period patient was treated with **ZYPREXA**, **ALCOHOL**. Patient was hospitalized. Patient died.

STRATTERA problem was reported by a Physician from CHILE on **Sept 04, 2007. Male patient, 14 years of age**, was diagnosed with attention deficit/hyperactivity disorder and was treated with STRATTERA. After drug was administered, patient experienced the following problems/side effects: **ventricular fibrillation**. STRATTERA dosage: unknown. Patient was **hospitalized**. Patient died on 07/01/2007.

Number of deaths 44

(33 of the cases reported by health care professionals; note Lilly told MHRA they had *a total* of 24 ADRs about death, from HCPs, up to November 2007.)

28 children and adolescents (-19); 15 of these suicides.
16 adults; 5 of these suicides.

This gives a total from the three sources:
Children: 16+15 suicides = 31
And a total of 55 children dead.

Adults: 21+5 suicides = 26
And a total of 47 adults dead

In total 57 suicides and a total of 102 deaths.