AUSTRALIAN GOVERNMENT WARNINGS & OTHER ACTIONS ON PSYCHOTROPIC DRUGS

The Therapeutic Goods Administration (TGA) is Australia's drug regulatory agency. They are responsible for authorising the sale of drugs and medical devices in Australia as well as their removal from sale if they are harmful to the public. They also conduct investigations into drugs and medical devices as well as issue warnings about drugs and medical devices.

Below are the warnings that the TGA have issued since 1995 with regards to psychotropic drugs along with other safety advisories, investigations the TGA have performed and information they and the Government have issued.

The strongest warning that can be placed on any drug in Australia is called a "Boxed Warning." In the US this is called a "Black Box Warning." Sometimes it is also called a "Black Box Warning" in Australia because the US use this term.

This Boxed Warning in Australia is **not** on the packaging of the drug and it is **not** on the "Consumer Medicine Information" (CMI) which is given to the consumer when they fill a prescription. The Boxed Warning is only on the "Product Information" (PI) which doctors, pharmacists and other health professionals use. It is called a "Boxed Warning" because this warning is placed in a text box within the PI. The information is also placed within the CMI but not in the exact same words and **not** within a box.

Therefore the consumer does not always know that the strongest warning that can be issued for a drug in Australia has been placed on the drug they are taking. It is left to the consumer to independently research the drug further themselves on the internet or in a library and locate the relevant PI for the drug. They can also ask their doctor or pharmacist for a PI or ask them if the drug has a Boxed Warning, if they are aware of these boxed warnings.

Even the CMI is not always given to a consumer each and every time they fill a prescription for a psychotropic drug and not all psychotropic drugs in Australia have information within their packets. The above situations can prevent the consumer from being fully informed at time of prescribing or filling a prescription. Coupled with the fact that not all psychiatrists inform their patients of all warnings and potential side-effects for the drug, patients are not always able to give fully informed consent for any psychotropic drug proposed as treatment.

All Boxed Warnings should be on the packet of the drug so consumers are easily able to be more fully informed.

Many consumers are also unaware that they can themselves report adverse side-effects directly to the TGA. To report an adverse drug reaction to the TGA: 1) on-line, log onto: https://www.ebs.tga.gov.au/ebs/ADRS/ADRSRepo.nsf?OpenDatabase
2) phone: 1300 134 237

CCHR is organising a petition to help change this situation and asks that the TGA require drug manufacturers to add a prominent boxed advice on the packaging itself informing consumers that they can report adverse side-effects directly. Correct reporting of side-effects can ensure that relevant warnings are placed on the drugs and can result in needed investigations into drugs with adverse reactions. Please email CCHR at national@cchr.org.au to obtain a copy of the petition to sign or log onto www.cchr.org.au

Side-effects reported to the TGA for psychiatric drugs in Australia: The TGA have a database of all the side-effects reported by doctors, chemists and the public for all drugs available on their website. It is very simple to generate side-effect reports for psychiatric drugs using this database. These reports generated include the number of deaths linked to the drug. Each time this is done for a drug, two reports are generated so do look at both of them. It is also a good idea to save the reports as they can then be fully searched for specific side-effects. See under "Adverse Events" on the TGA homepage or use this direct link for the database: https://www.tga.gov.au/database-adverse-event-notifications-daen

NOTE: Prior to 2010 the TGA issued "Adverse Drug Reactions Bulletins" containing drug warnings. Since January 2010 these have been called "Medicine Safety Updates."

WARNING: **No one should stop taking any psychotropic drug without the advice and assistance of a competent medical doctor.**

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2017

February – The TGA advised in a Medicines Safety Update that the antipsychotic aripiprazole (Abilify and other brands) can cause increased urges particularly for gambling along with the inability to control these urges. Other urges reported included increased sexual urges, compulsive spending and eating.[1]

2016

December – The TGA issued another Medicines Safety Update covering the increased risk of suicidal thinking and behaviour with antidepressants, particular SSRI's (a class of antidepressants). The TGA stated that several studies have shown that patients and carers have not received enough information about their drugs and the TGA strongly encourages doctors to give their patients the relevant CMI for the antidepressant prescribed. They also warned that antidepressants should never be suddenly stopped and should be reduced gradually [always under a doctor's supervision] to avoid potential discontinuation symptoms (also called withdrawal syndrome- worsening of current symptoms or new never before experienced symptoms) such as nausea, sleep problems, dizziness, irritability, anxiety, numbness and 'electric shock-like' sensations. [2]

2015

August – The TGA in a Medicines Safety Update advised that they had received 17 reports of cerebrovascular adverse reactions (stroke) for the antipsychotic risperidone (Risperdal). As far as dementia in the elderly is concerned, risperidone is now limited to treatment up to 12 weeks for moderate to severe Alzheimer dementia only. The new PI for risperidone also states that non-drug approaches should be used first. [3]

April – The TGA issued a Medicines Safety Update to warn of the risk of liver injury with the use of the antidepressant agomelatine (Valdoxan). The Product Information for agomelatine has been updated to state that it is recommended that liver function tests are done prior to prescribing and before increasing the dose. The TGA also advised that there should be close surveillance of liver function, including liver tests. [4]

2014

October – A TGA Safety Update advised that in rare cases methylphenidate (Ritalin and Concerta- ADHD drugs) may lead to prolonged and sometimes painful erections. A precaution for this has been added to the Product Information. The TGA also stated that the Product Information for atomoxetine (Strattera- ADHD drug) lists painful or prolonged erection as a potential side-effect. [5]

October – The TGA issued a Safety Update to warn of serious cardiovascular adverse events with the antidepressant bupropion (Zyban) used in smoking cessation. [6]

September – The TGA in a Safety Alert warned doctors to be alert for serotonin syndrome in people drugs used to treat nausea and vomiting who are also on antidepressants (serotonin syndrome occurs when the body has too much serotonin; symptoms may include restlessness, hallucinations, loss of coordination, fast heartbeat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting, and diarrhoea). In some cases the TGA said serotonin syndrome can lead to a loss of consciousness, coma and death. The TGA said doctors should advise patients and caregivers of the risk or serotonin syndrome. [7]

August – The TGA completed a safety review of the sleeping drug zolpidem (Stilnox). Subsequently the TGA recommended specific dose rates and warned of next day impairment including drowsiness. They also warned again of potentially dangerous side-effects such as sleep-walking, sleep driving and other bizarre behaviour related to zolpidem. [8]

February – The TGA issued a Medicines Safety Update regarding the antipsychotic quetiapine (Seroquel and its generics) because post marketing reports indicated that it can cause QT prolongation (a QT interval is part of the cycle of a heartbeat. A prolongation of the QT interval increases the risk of sudden death from abnormal heart beats). This has occurred not only with overdoses but also with concomitant illness (naturally accompanying or associated illness) and in patients taking other drugs known to cause electrolyte imbalances or increase the QT interval. A new warning in the Product Information (PI) advises that quetiapine treatment in combination with antipsychotics and other drugs known to increase the QT prolongation be avoided, particularly in the elderly. The TGA have received 807 adverse event reports for quetiapine including 2 reports of cardiac arrest. [9]

February – The benzodiazepine Alprazolam (Xanax and its generics) was made a Schedule 8 drug placing it in the same category as cocaine, morphine and opium. A Schedule 8 drug is a "controlled drug" meaning its use is restricted to reduce abuse, misuse and physical or psychological dependence. [10]

2013

December – A Medicines Safety Update issued by the TGA for the antidepressant duloxetine (Cymbalta and generics) to warn it can cause serotonin syndrome (serotonin syndrome occurs when the body has too much serotonin; symptoms may include restlessness, hallucinations, loss of coordination, fast heartbeat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting, and diarrhoea). The TGA has received 21 reports of serotonin syndrome in which duloxetine was the sole suspected drug. [11]

October – The TGA issued a Medicine Safety Update concerning the risk of suicidality in children with the non-stimulant ADHD drug atomoxetine (Strattera, an antidepressant) after the suicide of a 9 year old on the drug. The TGA have received 65 adverse event reports for psychiatric disorders associated with atomoxetine, 45 of these were reports of suicidal ideation with 28 of these for children younger than 18. There were 2 other reports for attempted suicide in children. The TGA advised that anyone prescribed atomoxetine should be monitored for suicidality. [12]

October – The ADHD drug lisdexamfetamine (Vyvanse) had a "boxed warning" placed on it to warn that is has the potential for abuse, misuse, dependence or diversion. The boxed warning also states that anyone prescribed the drug should be monitored for abuse and dependency.[13]

2012

June – A Medicines Safety Update issued by the TGA states that they continue to receive reports of potentially dangerous, complex sleep-related behaviours, amnesia and hallucinations associated with the sleeping tablet zolpidem (Stilnox) use. In 2007, a boxed warning was placed on the drug to warn of bizarre behaviours and despite the media and publicity surrounding this drug, adverse events have persisted at high levels. The Medicines Safety Update instructs that patients should be told of the risks and health professionals are encouraged to report adverse reactions to the TGA. [14]

February- The TGA issued a Medicine Safety Update concerning the risk of clinically significant increases in blood pressure and/or heart rate with the use of the non-stimulant ADHD drug Strattera (atomoxetine, an antidepressant). This issue of the Medicine Safety Advisory also warned again the antidepressant citalopram should no longer be used in doses above 40mg as it may be life threatening in higher doses. These follow on from the earlier safety advisories issued in November 2011. [15]

2011

November – The TGA advised that the antidepressant citalopram (Cipramil, Celapram, Talum, Ciazil, Citalobell, Celica and others with "citalopram" in their name) should no longer be used in doses above 40mg, for some patients no more than 20mg and others with a specific congenital heart condition should not take citalopram. Higher doses may result in life-threatening or fatal arrhythmias in some people. Stopping citalopram suddenly can cause withdrawal symptoms including anxiety, insomnia, emotional instability, headache, diarrhoea, vomiting and palpitations. [16]

November – The TGA issued a safety advisory regarding the risk of increased blood pressure and/or heart rate with the use of the non-stimulant ADHD drug atomoxetine (also known as Strattera, an antidepressant). Heart rate and blood pressure should be measured before treatment and monitored during treatment. [17]

October – The TGA issued a Medicines Safety Update to inform that the stimulant Modafinil (Modavigil) has had several safety changes and recommendations to the PI as a result of a TGA benefit-risk review after reports of serious skin, psychiatric, nervous system and cardiovascular adverse reports. These changes to the PI include warning that Modafinil has been associated with aggressive and hostile behaviour, suicidal ideation, suicidal-related behaviour, psychosis, mania, depression and ischaemic (reduced blood supply) heart disease in patients with a history of cardiovascular disease. [18]

August – The TGA in their Medicines Safety Update said that stress cadiomyopathy (deterioration of the heart muscle) may be an adverse effect of venlafaxine (antidepressant also known as Efexor). [19]

August – The TGA issued a Medicines Safety Update to warn that new born infants exposed to antipsychotics during the third trimester of pregnancy may be at risk of extrapyramidal signs (involuntary movements and muscle rigidity) and/or withdrawal syndrome. Adverse side-effects reported to the TGA for newborns include: breathing difficulties, tremor, agitation and muscle rigidity. All antipsychotics are now classed as pregnancy category C drugs. This means they are in the third most dangerous drug category and suspected of causing harmful effects on the foetus or newborn without causing malformation. These effects may be irreversible. All Product Information for antipsychotics is being updated to include this information. [20]

April- The TGA in their Medicines Safety Update Bulletin said that antidepressants appear commonly in suspected reports for drug-induced hyponatraemia (a lower than normal level of sodium in the blood which if severe can cause significant and permanent neurological injury or death). Commonly reported symptoms of hyponatraemia included confusion, Dizziness, dehydration, nausea and vomiting. [21]

February – The TGA issued in their Medicines Safety Update Bulletin a warning that if left untreated clozapine (an antipsychotic) induced constipation can lead to serious, potentially fatal complications. Health professionals should inform patients about the risk of constipation with clozapine. [22]

February – The TGA in their Medicines Safety Update Bulletin warned of a potential higher death rate amongst women who take tamoxifen for breast cancer and who also use paroxetine (antidepressant). It stated caution should also be taken with other SSRIs (a class of antidepressants). [23]

2010

December - The TGA in their Medicines Safety Update Bulletin issued a warning for drug-induced acute akathisia (the inability to remain motionless) particularly in patients taking antipsychotics. The inner restlessness and drive to move can result in significant distress. [24]

December - The TGA issued in their Medicines Safety Update Bulletin a 'reminder' on serotonin syndrome (serotonin syndrome occurs when the body has too much serotonin; symptoms may include restlessness, hallucinations, loss of coordination, fast heart beat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting, and diarrhoea) to warn that certain drugs including lithium, SSRIs, MAOIs (a class of antidepressant drug) tricyclic antidepressants and SNRIs (a class of antidepressants including Efexor and Cymbalta) can cause serotonin syndrome. Early signs and symptoms can be mild, yet life-threatening. Symptoms include: altered mental states – confusion, agitation, restlessness and excitement, as well as physical manifestations such as shivering, flushing, tachycardia (increased heart rate) and hyperthermia (elevated body temperature). Refer also to October 2009 entry above. [25]

December - The TGA issued a warning in their Medicines Safety Update Bulletin for lamotrigine (anticonvulsant used for epilepsy and bipolar) causing serious skin reactions which can be potentially fatal. Stevens-Johnson syndrome (a type of life-threatening severe rash) and toxic epidermal necrolysis (where the outer layers of the skin die) can develop following lamotrigine administration. The warning advises that lamotrigine is discontinued at first sign of rash unless it is obviously not caused by the drug. [26]

April - The TGA reported in their Medicines Safety Update Bulletin that their database contained 581 reports of drug induced pancreatitis (inflammation of the pancrease) including 35 for Valproate (an anticonvulsant used for epilepsy and bipolar). [27]

2009

December: The TGA released the final report of an independent Psychiatric Drug Safety Expert Advisory Panel established in 2008 by the TGA to undertake a scientific review of a series of cases submitted to the TGA by a psychiatrist and an extensive literature review of SSRIs and antipsychotics. Their recommendations included:

- The Product Information (PI) for reboxetine (antidepressant) should include advice about the potential for neonatal side-effects.
- The PI for all SSRIs should warn of the risk of Persistent Pulmonary Hypertension (high blood pressure in the lungs) for newborns.
- Consideration should be given to requiring all PI documents for atypical antipsychotics to recommend glycaemic monitoring regimes (used to monitor blood sugar levels) for those at risk of or those with diabetes.
- That the TGA should review consistency and appropriateness of advice in the PI of all SSRIs concerning monitoring patients at risk of diabetes or with diabetes.
- Consideration should be given to requiring PI documents of SSRIs and SNRIs (a class of antidepressants including Efexor and Cymbalta) to warn of serotonin syndrome during treatment (serotonin syndrome occurs when the body has too much serotonin; symptoms may include restlessness, hallucinations, loss of coordination, fast heart beat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting, and diarrhoea) during treatment. Treatment with the drug should be discontinued if symptoms of serotonin syndrome occur.
- Consideration should be given that the PI Documents of all SSRIs and SNRIs warn that they should not be used in combination with monoamine oxidase inhibitors (MOIA - a class of antidepressant drug which includes moclobemide). Cases of potentially life threatening serotonin syndrome have been reported in those on both drugs or those who have recently discontinued an SSRI/SNRI and started on a MAOI.
- They also recommended: There should be a standardized way in which important "drug to drug interaction" information is presented in the PI; The TGA should implement a program where Australian PIs are regularly reviewed for consistency with other international documents throughout the life of the PI for these drugs; The TGA should include items on serotonin syndrome in their upcoming issues of Adverse Drug Reaction Bulletins. [28]

October: The TGA issued an Adverse Drug Reactions Bulletin to warn that antidepressants have properties that predispose individuals to suffer adverse effects when switching antidepressants. Serotonin syndrome, a potentially life threatening condition, which occurs when the body has too much serotonin; symptoms may include restlessness, hallucinations, loss of coordination, fast heart beat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting, and diarrhoea is one of the adverse effects of antidepressants and can occur during treatment and during switching particularly in the elderly. [29]

August: The TGA issued an Adverse Drug Reactions Bulletin to warn that the antidepressant duloxetine, also know as Cymbalta can cause serotonin syndrome (serotonin syndrome occurs when the body has too much serotonin; symptoms may include restlessness, hallucinations, loss of coordination, fast heart beat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting, and diarrhoea.) The TGA said they have had 108 reports of suspected adverse reactions for duloxetine from June 2008 to May 2009 including 10 cases of suicidal ideation and 8 cases of agitation. From the evidence the TGA has, they say that serotonin syndrome can occur with duloxetine treatment alone even at normal doses as well as in combination with other drugs known to cause this syndrome. The Product Information for Cymbalta has been updated to include this information. [30]

April: The TGA reported in their Adverse Drug Reactions Bulletin some of the serious risks of sodium valproate (approved to treat mania). Specifically, that it is well known to cause foetal malformations and is classified as a Pregnancy Category D drug (drugs that have caused, are suspected to have caused or may be expected to cause an increased incidence of human foetal malformations or irreversible damage). These drugs may also have adverse pharmacological effects. [31]

February: A Boxed Warning (the strongest warning) was placed onto the ADHD drug Concerta by the TGA for drug dependence. It warns that chronic abuse of Concerta can lead to a marked tolerance and psychological dependence with varying degrees of abnormal behaviour and frank psychotic episodes can also occur. [32]

2008

December: The TGA issued an Adverse Drug Reactions Bulletin to warn that the stimulant-like drug, modafinil, can cause serious life threatening skin reactions and serious psychiatric reactions. The TGA recommends that at the first sign of rash or if patients experience psychiatric symptoms, modafinil should be discontinued and not re-started. [33]

October: The TGA reported they had received 307 reports of hyponatraemia (a lower than normal level of sodium in the blood which if severe can cause significant and permanent neurological injury or death) since May 2005. Antidepressants were the suspected cause in 78 of these reports. 101 of the total reports were severe and the most commonly associated drugs for severe hyponatraemia included carbamazepine (anticonvulsant) and the antidepressants, paroxetine (Aropax), venlafaxine (Efexor) and sertraline (Zoloft). Two thirds of the 307 reports received were for patients over the age of 70 and 70% involved women. [34]

February: The TGA imposed a Boxed Warning on the sleeping table Stilnox (zolpidem) after 1032 reports of adverse reactions to the drug. The warning instructs that the drug may be associated with potentially dangerous complex sleep related behaviours including sleep walking, sleep driving and other bizarre behaviours. Close medical supervision is needed. [35]

2007

August: The TGA issued an Adverse Reactions Bulletin about newer antipsychotic agents causing extrapyramidal side-effects - EPS (involuntary movements and muscle rigidity). There had been 70 reports for clozapine and 126 reports for olanzapine (Zyprexa). About one third of patients experiencing EPS had not recovered. [36]

August: The TGA's drug adverse reaction database revealed there had been 112 notified adverse reactions reports—in 67 separate cases—for antidepressant use among under 10 year olds. These included convulsions, mania, muscle spasms, hallucinations and insomnia. A further 807 adverse health responses, in 495 cases, had been linked to use by youths aged between 10 and 19 years. The reactions for 10 to 19 year olds include 4 deaths. [37]

June: The TGA issued an Adverse Reactions Bulletin stating that a range of cardiac disorders are associated with the use of the antipsychotic drug clozapine. A Boxed Warning alerting prescribers is on the product information. Prescribers should be warned that potentially fatal myocarditis (inflammation of the heart muscle) may develop after commencement of Clozapine. [38]

June: The TGA issued an Adverse drug Reactions Bulletin for the antidepressant Mirtazapine (Avanza) stating prescribers need to warn patients of potentially life-threatening neutropenia (condition where a type of white blood cells is low) and agranulocytosis failure of bone marrow to make enough white blood cells). [39]

April: The TGA issued an Adverse Reactions Bulletin stating that it appears that all of the atypical antipsychotics can cause neuroleptic malignant syndrome - NMS (abnormally high body temperature causing destruction of tissue which can be potentially fatal). They said they have received 85 reports of NMS for clozapine, 49 reports for olanzapine (Zyprexa), 45 reports for risperidone and there were another 46 reports for other antipsychotics. [40]

April 5: The Australian Therapeutic Goods Administration requested that the makers of the sleeping drug Stilnox (zolpidem) strengthen the current warning about mixing the medicine with alcohol. This request comes in the wake of more than 500 complaints about Stilnox including reports of sleepwalkers crashing cars, falling off balconies, smoking, painting and having sex after popping a pill. [41]

February: The Australian Therapeutic Goods Administration warned that zolpidem (Stilnox) has had a number of side effect reported, of which "75% of the reports received described one or ore neurological or psychiatric reactions, especially visual hallucinations, confusion, depression and amnesia." The Advisory Committee is recommending that people need to be alert to these possible side-effects, and doctors need to warn their patients about it. [42]

2006

October 18: The TGA ordered manufacturers of "ADHD" drugs, Ritalin, Strattera and dexamphetamine to add stronger warnings to their information packaging after receiving 200 adverse reaction reports about the drugs. The TGA had received 123 reports of adverse reactions involving Ritalin, including complaints that it caused headache, nausea, anorexia, somnolence and depression as well as 23 reports about atomoxetine (Strattera), including aggression, and 60 reports about dexamphetamine, including seven of agitation, five of tachycardia (rapid heartbeat) and four reports each of hypertonia (abnormally increased muscle tone causing rigidity), hyperkinesia (involuntary movements occurring continuously) and insomnia. [43]

March 14th: The TGA ordered a boxed warning (the most serious type of warning) for the risk of suicidal thoughts and behaviours be put onto Strattera, a non-stimulant drug prescribed for ADHD. [44]

2005

December: The TGA issued an Adverse Drug Reactions Bulletin stating that the antipsychotics risperidone, fluphenazine, haloperidol, clozapine, olanzapine, pimozide and thioridazine and the antidepressants amitriptyline, imipramine, clomipramine, dothiepin and doxepin can cause a QT prolongation effect. A QT interval is part of the cycle of a heart beat. A prolongation of the QT interval increases the risk of sudden death from abnormal heart beats and in this case the TGA said it can lead to a life threatening tachycardia (increased heart rate). [45]

September 7: The TGA issued an information sheet to health professionals warning that SSRI use—especially Paxil—in early pregnancy could cause congenital heart abnormalities in newborns. It reported that Danish researchers had determined the association in the first trimester of pregnancy. It recommended that patients not suddenly stop taking Paxil because "they may have withdrawal effects that can be severe or life-threatening. Dosage must be tapered off…." [46]

August: The TGA published an Adverse Drug Reactions Bulletin reporting a review of SSRIs found evidence supporting an association between SSRI use and "new onset of suicidality" (the likelihood of an individual completing suicide) in *adults*. It usually developed shortly after commencing the drugs or after an increase in dosage that could cause akathisia, (the inability to remain motionless) agitation, nervousness and anxiety. Similar symptoms could also occur during *withdrawal.* [47]

2004

December: The TGA published an Adverse Drug Reactions Bulletin recommending that any use of SSRIs in children and adolescents should be carefully monitored for the emergence of suicidal ideation. In a recent study involving Prozac, it said, there was an increase in adverse psychiatric events (acts and ideation [thoughts] of suicide, self-harm, aggression, violence). [48]

October: The TGA ordered a new warning be added to the Product Information for tricyclic antidepressants to warn of the risk of suicide by overdose after high dose presentations that can be obtained by patients have been associated with some patient deaths from overdose. [49]

June: The TGA published an Adverse Drug Reactions Bulletin reporting that the latest antipsychotics could increase the risk of diabetes. [50]

February: The TGA reported they had received 161 reports of serotonin syndrome. Serotonin syndrome occurs when the body has too much serotonin; symptoms may include restlessness, hallucinations, loss of coordination, fast heart beat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting, and diarrhoea. It is potentially serious. SSRIs, venlafaxine (Efexor) and tricyclic antidepressants can cause this syndrome. In the majority of reports, the signs and symptoms developed within 24 hours of the addition of another serotonergic agent or an increase in dose of an agent. The TGA said health professionals should note that they can cause this and should inform patients of the risk when seretonergic agents are prescribed. [51]

2003

October: The TGA reported that new antidepressants Remeron, Avanza and Mirtazon could cause potential serious reactions such as convulsions, blood clots, anxiety, agitation, blood disorders, nightmares, and hallucinations. [52]

August: The TGA reported that the use of SSRIs during or after pregnancy may result in adverse reactions to newborn babies, due to the withdrawal effect following intra-uterine exposure, or a toxic effect from ingestion of an SSRI in breast-milk. The withdrawal effects the baby experienced included agitation, jitteriness, poor feeding, sleepiness/lethargy, gastrointestinal symptoms and hypotonia (deficient muscle tone or tension). [53]

June: The TGA reported that as a group, SSRIs account for about one-quarter of all reports of hyponatremia (a lower than normal level of sodium in the blood) received by the Australian Drug Reactions Advisory Committee, and are second to diuretics as the group most commonly associated with hyponatraemia . In about two-thirds of cases, full recovery followed withdrawal of the SSRI and fluid restriction. Three cases had a fatal outcome related to hyponatraemia. [54]

2001

February: The TGA reported that SSRIs have an association with raised internal pressure within the eye. [55]

2000

February: The TGA published an Adverse Drug Reactions Bulletin reporting that psychiatric drugs can cause nightmares and specifically mentioned Prozac, Zoloft, Paxil and Celexa. [56]

1999

December: The TGA reported that SSRIs and tricycle antidepressants can cause constipation. 15 reports have also been received for the antipsychotic clozapine and of these 9 were described as severe. [57]

August: The TGA issued an Adverse Reactions Bulletin to warn that olanzapine (Zyprexa) can cause serious problems such as white cell disorders, convulsions and neuroleptic malignant syndrome (abnormally high body temperature causing destruction of tissue). They also said that weight gain and somnolence (excessive sleepiness) were the most commonly reported side-effects. To date they had received 327 suspected adverse reactions to the drug. [58]

1998

August: The TGA issued an Adverse Reactions Bulletin on SSRIs such as fluoxetine (Erocap, Lovan, Prozac, Zactin), paroxetine (Aropax) and sertraline (Zoloft) stating they have been associated with bruising and bleeding. [59]

February: The TGA issued an Adverse Reactions Bulletin reporting that venlafaxine (Efexor), an antidepressant drug appears to have a greater association with nausea/vomiting/anorexia, headache, increased sweating**,** syncope (fainting caused by a cardiovascular disorder) and hypertension than the SSRIs. [60]

1997

November: The TGA issued an Adverse Drug Reactions Bulletin concerning neonates whose mothers had taken SSRIs throughout their pregnancies and have experienced withdrawal reactions. Reports included a 3 day old baby who developed jitteriness, fever and anorexia. Another baby was treated for rapid breathing and irritability for 2 days after it was born. These reports suggest that adverse reactions to SSRIs can occur in neonates, through either placental or breast milk transfer. [61]

1996

August: The TGA issued an Adverse Drug Reactions Bulletin on adverse effects of SSRIs. They said the selective serotonin reuptake inhibitors (SSRIs), fluoxetine (Lovan, Prozac, Zactin), paroxetine (Aropax) and sertraline (Zoloft) are associated with a variety of adverse effects. They found that 2 of the unusual types of adverse effects were urinary problems and sexual dysfunction. [62]

February: The TGA issued an Adverse Drug Reactions Bulletin stating SSRIs have been associated with withdrawal syndrome. The

symptoms most commonly reported on withdrawal were dizziness (15 reports) and nausea (10). Anxiety, headache (both 5 reports), agitation, insomnia, increased sweating, tremor and vertigo (4 of each), hallucinations, and depersonalisation (3 of each) were also described. There was a total of 51 different symptoms documented in the reports with a wide range of other neurological and psychiatric symptoms including amnesia, ataxia (unstable gait), blurred vision, confusion, dysarthria (dis-coordination of the speech muscles), delirium, fatigue, hyperacusis (abnormally acute hearing), hypertonia (abnormally increased muscle tone causing rigidity), meningism (spasms of the neck muscles caused by inflammation of the membranes around the brain and spinal cord), mood swings, neurosis, nervousness, nightmares, paraesthesia (abnormal skin sensation eg burning sensation in the skin), rigors, sensory disturbance, tinnitus (ringing in the ears), and twitching. There was also a report of a neonatal withdrawal reaction. [63]

1995

November: The Australian Therapeutic Goods Administration (TGA) issued an Adverse Drug Reactions Bulletin stating that they had received 109 reports of drug- induced pancreatitis and the most commonly reported drugs in association with this included the antipsychotic clozapine and yet this was not at the time listed as a possibility in the Product Information for the drug. [64]

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CCHR was established in 1969 by the Church of Scientology and Professor of Psychiatry, Dr Thomas Szsaz to investigate and expose psychiatric violations of human rights.

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