THERAPEUTIC GOODS ADMINISTRATION

Grievance

MR M.P. WHITELY (Bassendean - Parliamentary Secretary) [9.39 am]: My grievance is to the Minister for Health. I would like the minister to use whatever influence he has with his federal counterpart, Tony Abbott, to get the Therapeutic Goods Administration to do its job properly. The TGA is supposed to be the watchdog that protects pharmaceutical consumers, particularly our most vulnerable consumers, children. The TGA has failed abysmally and Tony Abbott is asleep at the wheel. Perhaps the clearest example of this systemic failure is the TGA's hopelessly inadequate handling of the attention deficit hyperactivity disorder drug, Strattera. Strattera is Eli Lilly's brand name for atomoxetine hydrochloride, a noradrenaline re-uptake inhibitor. It was first developed as an antidepressant called Tomoxetine, but was found to be ineffective. Nonetheless, Lilly was determined not to waste its product development expenditure and rebranded Tomoxetine as Strattera, calling it a revolutionary, non-stimulant ADHD drug. Strattera's marketing advantage is that, unlike dexamphetamine and Ritalin, it is not a stimulant and is therefore the only non-addictive ADHD drug available, and it has no possibility of being diverted for illicit use.

Strattera was first approved for the treatment of ADHD in the United States by the Food and Drug Administration in late 2002. It was approved in Australia by the TGA about a year later. There has been and continues to be a lot of positive hype around Strattera, partly because of the increasing and valid concerns about the safety of dexamphetamine and Ritalin. In December 2003, I visited Eli Lilly's office in Sydney to hear its Strattera pitch. I had an open mind and was hoping for a harmless alternative to dexamphetamine and Ritalin; however, I was disturbed to encounter the reluctance of Lilly's three representatives' to answer one very simple, straightforward question: what are the side effects or dangers of Strattera? I became suspicious as a result of that reluctance, and it did not take a long time to have my suspicions confirmed. On 17 December 2004, the US FDA issued a paper entitled "New Warning for Strattera", which stated -

> The labelling is being updated with a bolded warning about the potential for severe liver injury . . .
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> The labelling warns that severe liver injury may progress to liver failure resulting in death or the need for a liver transplant . . .

At the same time as the FDA took action, the TGA made some softly worded changes to the consumer medical information, but, unlike the FDA, it made no public announcement and issued no press releases. The TGA's changes to the CMI used far less direct language than that used in the US FDA's warning.

Liver damage is not the only danger from Strattera. Like all ADHD drugs, it has a range of potentially nasty side effects, including suicide. On 29 September 2005, less than a year after the liver damage warning, the FDA issued a public health advisory notice that it had put the highest possible warning - a boxed warning - on Strattera of suicidal ideation. As well as publicising the warning, the FDA insisted that specific information about these dangers be provided when every new prescription is filled. In contrast, the TGA did very little. Although it put a black-box warning of suicide on Strattera on 19 March 2006, it did almost nothing to inform the public of this. Even the term "black-box warning" is extremely misleading. Until recently, I mistakenly assumed that it was a prominent warning written in black on the outside of drug packaging. However, I was mistaken. In reality, it is the warning on the product information sheet that is available only to doctors, not patients or parents. Apart from the inadequate, hard-to-find, softly worded information in consumer medicine information, there is no mechanism for ensuring that parents and patients are informed.

The TGA had no excuse for its half-baked response. It had plenty of evidence of the dangers of Strattera, highlighted in a sample of 30 adverse reports that the TGA has received in the past few years. I will paraphrase some of them. Reports on the effects of Strattera indicated the following: an 11-year-old boy wanted to kill himself; a seven-year-old girl tried to kill herself; an 18-year-old male suffered swollen, painful and tender testicles; and a 24-year-old woman wanted to kill herself. Another report that I find extremely disturbing refers to a 12-year-old-girl who experienced "anorexia, weight loss, fidgeting and compulsive behaviour that included ripping out fingernails and toenails, picking and cutting clothing, and anger outbursts". Six days after commencing Strattera a seven-year-old girl was "seeking attention and wanted the focus to be on her. She became very agitated while travelling in the family car and had explosive mood swings. She said that she intended to open the door and get out of the car, and she tried to open the car door. The mother confirmed that the drug was not effective". A nine-year-old boy "developed abnormal behaviour, including strange facial expressions with bilateral eyelid ptosis and became very emotionally withdrawn"; another nine-year-old boy experienced "aggression, was totally irrational for three days and became violent, all of which was totally out of character"; an 11-year-old by "became agitated, emotionally labile and experienced thoughts of self-harm"; and a 13-year-old boy "experienced chest pains and hostile and aggressive behaviour, but the problems immediately disappeared with the cessation of Strattera".

My grievance is obviously directed towards the federal government, but I would like the minister to use whatever influence he has with the federal government. The TGA has done almost nothing to warn parents that Strattera could cause their children's liver to fail or cause their children to want to kill themselves. Its approach to Strattera is just one example of the TGA's failure to protect consumers. From January to September 2005 the US FDA issued 20 boxed warnings for drugs sold in both the US and Australia, while the Australian TGA issued warnings for only five of these 20 drugs. In response to a question on notice in the Senate the TGA admitted that it does not even bother to monitor the FDA's policies. In both countries the drugs are the same and the children are the same, and the effects of Strattera on them are the same, so the TGA should be doing that monitoring. The US FDA does the job far better than the Australian TGA does. That does not mean to say that the US FDA does the job well at all. In fact, some recent revelations from whistleblowers in the FDA have been about how cosy the drug companies are with big pharmaceutical companies. Putting that aside, the FDA's approach is still streets ahead of the TGA's approach. Responsibility for the abject failure of the TGA rests fairly and squarely with Tony Abbott.

MR J.A. McGINTY (Fremantle - Minister for Health) [9.47 am]: This is a very important matter affecting the health and, indeed, the lives of a significant number of young people. I therefore thank the member for Bassendean for raising it. Strattera, or atomoxetine, is a non-amphetamine drug used to manage ADHD. It has been shown to increase the risk of suicidal ideation and liver damage. Atomoxetine is approved in Australia for the treatment of ADHD for children six years and older, adolescents and adults. Some of the examples the member for Bassendean gave, particularly those in which suicide became an issue in connection with taking the drug, it is obvious that very young people are, in a sense, the victims of the use of this drug. Short-term comparative studies of this medicine with placebo revealed an increased risk of suicidality in children taking atomoxetine. As a result of this and of some of the initiatives that the member for Bassendean has referred to in the United States Food and Drug Administration's approach to this drug, in March 2006 the Therapeutic Goods Administration added a black-box warning to atomoxetine product information regarding the risk of suicidality in children and adolescents. Adverse reactions to any prescription medicine should be reported to the adverse drug reaction unit of the Therapeutic Goods Administration.

In essence, the issue that the member for Bassendean has raised this morning is his belief that the Therapeutic Goods Administration has not publicised the risks of Strattera enough, particularly when findings about the side effects arose. Secondly, he feels that it is an example of the Therapeutic Goods Administration's lack of rigour in its approach to consumer safety. Thirdly, he feels that the US Food and Drug Administration is much more rigorous than the Therapeutic Goods Administration, demonstrated by the greater number of black-box warnings it issues. As a result of those three issues, the member for Bassendean believes this is a matter that should be formally raised with my good friend the federal Minister for Health, Tony Abbott, next time that opportunity presents itself.

I will make some general observations about Strattera medication. All medicines have potential side effects that must be considered as part of the treatment. Before prescribing medicines, doctors will assess the risk of the potential side effects against the expected benefits of the medication. Before being approved for supply in Australia, medicines are thoroughly assessed for their safety, quality and effectiveness. This process is the responsibility of the Therapeutic Goods Administration of the Australian government's Department of Health and Ageing. As part of the approval process, sponsors provide a detailed application, including clinical safety and efficacy data, which is evaluated by the TGA.

Prescription medicines are provided with detailed product information to ensure the safe and effective use of medicines. Adverse reactions to any prescription medicines should be reported to the adverse drug reaction unit of the TGA. As a prescription-only medicine included in schedule 4 of the Poisons Act 1964, the Department of Health imposes strict regulatory controls over who may access, sell and supply atomoxetine in Western Australia. Atomoxetine may be prescribed only by registered medical practitioners and is available only through pharmacies. There are additional regulatory controls over the prescription and supply of dexamphetamine and methylphenidate in Western Australia. We, as a government, and I am sure the whole Parliament, support the current national system of assessment and registration of medicines. That is not to say that sufficient has been done in dealing with this matter.

In the federal Parliament this year, a question was posed of the federal Department of Health and Ageing by Senator Scott Despoja. It asked what action the department had taken in dealing with Strattera following the placement by the United States Food And Drug Administration of a black box warning on the drug for liver damage and a bolded warning for suicide. The answer was provided in the budget estimates that were held between 31 May and 1 June 2006. It was as follows -

> Information on the hepatic effects of Strattera was added to the precautions section of the product information document for Strattera in December 2004. The Precautions section of the product

information (PI) also cross-references Hepatic Impairment to the Pharmacology, Pharmacokinetics, Special Populations and Dosage and Administration sections of the PI.

The Consumer Medicine Information (CMI) document advises that before taking Strattera patients should notify their doctors if they have or have had liver disease. In addition, the CMI States that in rare cases the drug can cause liver damage and advises patients to tell their doctor as soon as possible if they notice any of the following signs of liver injury - dark urine, yellowing of the skin or eyes, severe cramps in the stomach, or unexplained nausea, fatigue, lethargy, itching or flu-like symptoms.

The TGA considered the issue of strengthening the existing precautionary statements in the PI regarding suicidality in children and adolescents treated with Strattera (atomoxetine) and consulted with the Australian Drug Evaluation Committee (ADEC). As a result, a black box warning was added to the PI by the TGA on 14 March 2006.

That was the response in the federal Parliament when this most important matter was raised. I will undertake, in the light that inadequate information poses a risk to children who are prescribed the drug for the treatment of ADHD, to provide to the federal Minister for Health and Ageing a copy of the *Hansard* of this debate and request that he take stronger action in the interests of protecting our children.