PE1651/UUUUUUU
Anonymous submission of 10 February 2018

I believe that Antenex (Diazepam) and many other classes of antidepressants, are not deemed safe and should therefore be completely taken off the market.
The reason why I say this is because of the following:

I believe my husband and I ingested a flawed batch, which caused a long list of health issues we have today.
I believe the reason why I have not dealt with my problem, which stems back to 16 years ago, when I experienced severe health issues with diazepam, is due to :
No medical professional was willing to come forward and state the truth of what had happened to me.
Everything was covered up.
Everything was downplayed.
Why, I will never know??????

Many treated me like a pin cushion.
Some clinicians were very disrespectful towards me, including some nurses.
There were some Specialists who wanted to do more invasive tests, such as having dye injected in the vessels of my brain to determine if I had gone through aneurysm~ this is when I called it quits! I said enough is enough!!!!!!!!
I did not want to be HARMED, anymore.

This one poison:
- Ruined my good health.
- Ruined any chances of ever conceiving.
- Ruined my ability to ever go back to work full time
- Stole the best years of spending time with my family and friends. Just wanted to be in total isolation because I was feeling very ill, all the time. Felt like I was always in a daze. This is how poor people with Alzheimer's must feel.

I believe certain medicines induce Alzheimer's especially when these medicines cause plaque deposits or induce severe cerebral aneurysm in some sections of the brain ~ my theory.
- Stripped away my dignity, self-esteem, happiness and confidence.
- Left me with debilitating residual health problems

My poor health has impacted everyone's life

That dreadful night, which I do not want to recall, I knew that something horrible had happened to me. I believe I experienced a life threatening adverse reaction to diazepam.

The pain and pressure in my head was too intense.
My heart was racing like it was going to jump out of my chest.
I believe that a small vessel of my brain had raptured.

To get myself out of this terrible pain, I believed that if I consumed lots of alcohol, the severe pain and pressure in my head would subside.
As I guzzled one bottle after another, I believed that it would be best for all concerned, if I ended my misery.

I would not have to be a burden to anyone.

I had lost complete vision for a minute or so.
I felt very lightheaded and dizzy.
I felt tremendous chest pain.
I could feel my heartbeat slowing down.
I crawled into bed and prayed that it would be an instantaneous death.
I woke up feeling very bad the following day.
I was very angry with God.
What did poor God have to do with what I was going through?
My plan to end my miserable life unfortunately, failed!!!!!
I was doomed and I don't know how long I would be able to tolerate the pain and pressure in my head.
This is why euthanasia is wrong.
Someone like me could end their life when the going gets tough and not know what good things await for them.
Another issue that seriously needs to be addressed before changes in our Laws are made.

Anyway, getting back to the point:
It felt like there was a kink in one of the blood vessels of my brain.
The intense pain and pressure was too much to handle.
When I was so upset, I would pull strands out of my head. This is when I noticed blood on the tips of my hair strands.
Bleeding on the brain was what I believed I had experienced, together with nerve damage. Nerve damage of the brain is very hard to diagnose.

Then there was the nightmare of finding out what had caused all my health problems.
The ENT tests were very torturous.
Then more tests upon more tests were administered.
What a hell of a time I was enduring?
MRI scans, echocardiograms and many other tests, failed to show up what I was suffering from.
There was a high level of inflammation in my blood tests but no one could tell me why I was experiencing so much pain and pressure in my head.
One neurologist said that I might have meningitis.
One dear cardiologist said I had experienced enough but could not tell me what was happening. I was initially diagnosed with mitral valve prolapse and then after the horrible experience with diazepam this heart condition no longer existed.
I believe the kind cardiologist was saving me from taking any further medicines especially, antibiotics. Anymore medicines, I am certain I would have died.
I will never forget the time the nurses ignored me on the ward, when I was admitted into hospital for cardiac arrhythmia. How humiliating?

This diazepam really impacted my entire life.
At one stage my heart would skip beats and this was due to the anaphylactic reactions I was experiencing to foods and drinks. (additives, preservatives, colours, numbers etc. did not agree with me

I had to quickly learn what I had to eat and drink to survive.
I drank pure water and ate bland rice for the next seven months, until I understood what was going on with my health.
I had a long list of other medicines in my body before diazepam was prescribed and I believe the diazepam was the straw that broke the camel's back.

Why do I come up with this conclusion?
Twist to story ~ My poor husband ingested a Valium when he could not cope with what was happening to me and he also ingested one tablet out of the same batch I ingested. He had a heart attack.
Perhaps, these medicines induce vascular problems which causes so much disability or cause many unnecessary deaths.
Coincidental????
You be the judge!
I have a gut feeling that these medicines cause more problems than what they treat and consumers need to know about stories like myself.
I have never had severe anxiety or other abnormal health problems, until I popped a diazepam. What the hell was I thinking? Did it take my earache away?
When you mix these medicines with vaccinations, antibiotics, serc, radiation etc. what effects do they have on a cellular level of the body????
You be the judge!

The medicine I ingested + other class of antidepressants, are not fit for humans. They harm and damage peoples good health and wellbeing.
My story can be anyone's story however, many are not with us today because they were not so fortunate.
If a positive outcome can come out of my experience to benefit future generations, I believe I have fulfilled my purpose.

I would love to see the following recommendations take place:

- I would like to somehow receive an acknowledgement that the medicine I ingested nearly cost my life and resulted in unnecessary pain and suffering
- Cement recommendations that can be put into our laws/legislations to make medicines safe. Policy makers need to review the safety standards of medicines Worldwide. More controls are needed to prevent people from suffering the way I did. There needs to be severe changes on a state/federal/global level to prevent unnecessary suffering and destroyed damaged lives.
- We need to make the community aware of the dangers of ingesting unsafe, contaminated or tampered with medicines
- improve health services and give people decent levels of care when they are very sick and suffering in pain. Western medicine combined with some alternative medicine is creating great benefits for many people. Euthanasia is not the answer. If I didn't work hard to survive and took the easy option of ending my life I would not have had this extraordinary opportunity to make an enormous impact for everyone. It was a blessing bestowed upon me to be a beacon for many great changes

- Drug companies need to be accountable if a medicine is contaminated or unsafe. There is too much suppression of information on medicines and vaccines. When a tragedy such as mine occurs, we lose all civil rights.
- Establish an adverse reaction body group to better support people experiencing enormous difficulties.
- Peoples finances are shaken when one becomes ill and cannot return too full time work. Everyone's life is impacted by a sudden illness ,disability or death. Reforms of some kind should be put in place so people do not have to worry about money when one is very sick. Private health covers should include payments for accidental injuries and ongoing rehabilitation if needed. When families have financial worries this kind of setback puts everyone in the Red.
- From my understanding, there have been many coronal enquiries into the death of people who have died from strokes after taking the medicine my husband and I ingested (valium-diazepam). It is a known fact that this drug damages the short-circuit of the brain. There is also known proof and evidence that it causes brain damage. I would like to see a 'black box' warning on this drug and other anti-depressants that are known to cause severe problems. This is the label that I would like to see:

WARNING VALIUM AND MANY OTHER ANTIDEPRESSANTS MAY CAUSE POSSIBLE:
-suicide
-stroke
-brain damage
-panic attacks/anxiety

- There needs to be a constitution that protects everyone from harm. No one should have to suffer the same tragedy I went through. Supportive measures need to be put in place so that urgent medical assistance is provided.

- There needs to be an avenue for people to complain when the need arises. Sweeping things under the carpet is not the answer. There is no data to investigate claims like mine. Drug companies do need to disclose this kind of information. There needs to be laws that allow people to know the full truth of adverse drug reactions of medicines. People's fate should not be treated as a Russian roulette game.

- The people need to be made aware of unsafe/contaminated batches of medicines. For example: let us say that out of one million, there may be a batch that is contaminated or unsafe. Firm laws are required to prevent this from happening. There needs to be a dialogue based on justice and community awareness. Drug companies are not disclosing the serious adverse effects to the people. Should one have to have an impending thought of doom and gloom every time they ingest a medicine. "Why should a faulty batch of medicine alter the course of someone's life for the worse?"

- Doctors and specialists need to be thoroughly educated about the risks these medicines cause especially when combined with other medicines.

- Refer to recommendations I would love to see come about as a result of my experience I would love to see many changes implemented in our processes and systems. If there is a way of achieving these outcomes, I feel that my experience has not been a futile one. I am not hungry for power nor do I wish to have my name flashed on tabloids or have the media make a frenzy of me. I am what you call a quiet achiever who wishes to remain working behind the scenes for all to enjoy and benefit. Working together on a dream of mine would be the equivalent of winning the lotto. In the end it is not about financial rewards it is about bringing about great changes so that we can all benefit from someone's misfortune which is interpreted as 'a gift in strange wrapping paper', as one wise doctor quotes. It would also bring me great joy and comfort to know that another person does not have to suffer in silence and pain.

I look forward to the positive changes.

My journey has not been an easy one but I am hoping that whatever little I have done has been worth the fight. Acknowledgement from the Australian Government for what my husband, I and many have been through, would be appreciated.

In 2013, I petitioned the Australian Parliament on legislation to improve consumer safety by requiring warnings and results of all clinical trials to be included in pharmaceutical labelling and information[1].

The response provided to the Standing Committee on Petitions from the then Minister for Health is reproduced in the Annexe to my submission[2].

Annexe

[1] http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22chamber%2Fhansardr%2F9526da6b-9674-4509-a6d5-a7115a7c1f1a%2F0013%22

[2] http://data.openaustralia.org.au/origxml/representatives_debates/2013-12-12.xml

The Hon Tanya Plibersek MP
Minister for Health, Minister for Medical Research
Response to Standing Committee on Petitions

All clinical trials that meet the WHO/ICMJE 2008 definition of a clinical trial are required to be registered on the Australian New Zealand Clinical Trials Registry. This must occur before the first patient is enrolled in the trial.

In Australia, publicly funded research funded by funding bodies such as the National Health and Medical Research Council (NHMRC) must be conducted in accordance with the Australian Code for the Responsible Conduct of Research, 2007 (the Code), and, for research involving humans, with the National Statement on Ethical Conduct in Human Research, 2007 (the National Statement). These documents establish robust standards for the approval and conduct of research in Australia.

The Code guides institutions and researchers in responsible research practices. The National Statement promotes ethically sound human research by providing guidance on the design, review and conduct of human research. –

While neither document provides a legislative mandate, the conduct of NHMRC funded research is tied to a funding agreement such that any funded research must be carried out in accordance with the Code and the National Statement.

In relation to the provision of negative results from clinical trials, Section 4 of the Code acknowledges that dissemination of research findings is an important part of the research process and that researchers have a responsibility to their colleagues and the wider community to disseminate a full account of their research as broadly as possible. It also states that the account should be complete, and, where applicable, include negative findings and results contrary to their hypothesis.

The National Statement provides guidance for interventions and therapies, including clinical and non-clinical trials and innovations. In addition, the National Statement provides guidance on reporting requirements in relation to adverse events that may occur during research involving humans such as clinical trials. The events must be reported to the Human Research Ethics Committee by those conducting the trial.

In order for a new prescription medicine to be approved in Australia it is necessary for a sponsor to make an application to the Therapeutic Goods Administration (TGA). The application must be accompanied by supporting data to establish the quality, safety and efficacy of the medicine for its intended use.

A comprehensive evaluation of the submitted clinical and other scientific data is undertaken by the TGA and it is expected that all relevant data is submitted. Sponsors submitting an application for registration are required to provide a summary of the adverse events which occurred or worsened in the clinical trial patient populations. These are required to be summarised in tables listing each event, the number of subjects in whom the event occurred
and the frequency of the events in the patients treated with the drug under investigation, with comparator drugs and with placebo. A separate section is

included which details any deaths which may have occurred during the trial or post-trial completion which may have resulted from a process that began during the trial. It should be noted that adverse events occurring in a clinical trial are not necessarily causally related to the drug.

Where people with particular characteristics have suffered serious or life threatening side effects, these characteristics can be documented in the contraindications and precaution section of the Product Information (PI). For example, the clinical trial may highlight that people of a certain age and gender or people with conditions such as high blood pressure or particular organ diseases have suffered side effects to the point that the PI will provide advice to medical practitioners about the use of the medicine by these particular people.

Further, when advice about a prescription medicine application for registration is sought by the TGA from the Advisory Committee on Prescription Medicines, sponsors are required to submit tabulation of any serious unexpected adverse drug reactions that are not mentioned in the proposed Australian Product Information and have not been submitted previously. This can also lead to precautionary advice being included in the PI.

The PI document provides health professionals with a summary of the essential scientific informatron to alluw the safe and effective use of a me dicine under nearly all circumstances.

As a condition of registration, certain medicines, mainly those prescribed by a doctor, are required to have a product information document which provides information relating to the safe and effective use of the medicine, including information regarding the medicine's potential side effects and interactions with other medicines. PI documents are agreed with the TGA as part of the medicine's approval process before it can be made available in Australia.

The Consumer Medicines Information (CMI) is a leaflet that contains information on the safe and effective use of a medicine, including relevant and extensive information on side effects and interactions with other medicines. The information has been written by the pharmaceutical company responsible for the medicine. TGA regulations require that the CMI must be made available to consumers either in the pack or in another manner that will enable the information to be given to the person to whom the medicines are administered or otherwise dispensed.

The information in both these documents assists doctors, pharmacists and other health professionals in prescribing and dispensing medicines and also in their consultations with patients, such as to better educate a patient on the medicine they are being given.

The TGA recognises that not alladverse events which may be related to a medicine will occur within the context of a clinical trial. Therefore it conducts extensive post-market monitoring activities on medicines and regularly reviews adverse event signals which appear to be extra ordinary. This may lead to further information on adverse events being included in the PI and CMI documents.