Boxed Warning Guidance: Public Consultation Paper

Response by Australians For Safe Medicines
31 August 2018

Important Disclaimer:

Australians for Safe Medicines notes that the experiences of individuals cited in this submission include experiences of harm and distress. Australian for Safe Medicines reminds all its members and associates of the importance of making truthful and accurate statements about their experiences, but we cannot accept responsibility for the confidential and anonymous statements made by individuals in this submission or the legal risks that may arise from those statements.

About Us

Australians for Safe Medicines is a consumer-led association aimed at improving medicine safety.

We seek to empower the consumer to make informed decisions on medicines and enable them to voice their concerns about medicine safety (including unsafe prescribing practices and the need for new medicines.

We welcome the opportunity to comment on the public consultation paper from a consumer's perspective and welcome any efforts by the Therapeutic Goods Administration (TGA) to improve medicine safety.

Consumer Survey

"[Boxed Warnings] should be in place already. I can't understand how something so simple yet helpful is not in place. "

We surveyed our supporters via our website on key issues in your proposal. The survey results (excluding individual comments) are included from page 14.

We received 116 responses (we only had one week and were still receiving responses at the time of finalising this document). Here are the results:

- 90% have been harmed by medicines due to lack of warnings.
- 87% were not told that their medication could cause serious harm prior to taking it.
- 11% were warned by their doctor, and 3% by their pharmacist.
- 67% were not given any product information.
- 25% were given the leaflet in the box. 18% were given a print-out from the computer.
- 88% thought warnings should be placed on both the box and the leaflet in the box.
- 84% would be confused about warnings if they were only put on new medicines.
- 96% want pharmacogenomic information included on the boxed warnings.
- 73% did not know how to make a report to the Therapeutic Goods Administration.
- 93% would be more likely to report an adverse event if the form was provided with the medicine.

In addition, we asked consumers what they wanted you to know and representative quotes are included throughout this document.

We also asked consumers to speak up about their experiences. Their experiences are outlined from page 18.

We implore you to read these individual experiences to get a real understanding of the existing systemic problems that are not self-evident in mere statistics.

The Consumer Is Paramount

> ***"Right now there seems to be either gross neglect/apathy, lack of communication/education when it comes to prescription medicines and what the guidelines are, compared to what ends up happening the majority of the time."***

The National Strategy for the Quality Use of Medicines acknowledges the wisdom of the consumer experience, perceives them as the primary stakeholder, and requires that the consumer's wellbeing is foremost in the quality use of medicines.

The results of our survey, when combined with the wisdom of the consumer stories, suggest that Australia is failing in the implementation of this strategy.

Our survey results suggest a systemic failure by stakeholders to communicate with consumers.

Communication not only needs to happen, but needs to happen at all key touch points of the consumer, rather than the touch points of the stakeholder. For example, blue-cards need to be with the medicine not on the TGA website.

Many of our concerns with the proposal guidelines are that they appear to subjugate the consumer in nearly all aspects. Putting the consumer at the centre of the strategy is paramount to achieving the quality use of medicines.

Existing Risk & Harm

> ***"The idea that pharmaceutical companies do not have to provide "Clear and Explicit Warnings", knowing they have the skill, care and knowledge to do so does not speak to the industry alone, rather it speaks to the Regulators and the perception that Regulators and Legislators have been captured by influential lobby groups. Thus, poisoning does not only occur at the individual level, rather a cultural level too. Clear, Explicit Warnings must be a pre-requisite for all medications. After all, patient safety should be the imperative, not profit margins. In saying this, the Pharmaceutical industry does have and should continue in the development of medications. Indeed, the Pharmaceutical Industry has contributed to the overall health of the community, but this achievement should not be a license for them to treat consumers as lab rats, publishing journals such as Study 329, that have been demonstrated to harm children. Why the TGA has not advocated for the safety of patients, perhaps ties into the point I raised above, that is, Captured Regulator, or the perception of such."***

The World Health Organization has identified that unsafe medicines are a major worldwide issue and has announced "Medication Without Harm" is their current major patient safety initiative.

Numerous American, British, and Australian studies repeatedly show unsafe medicines to be amongst the top 4 causes of death and disability. [1][2][3][4][5]

In Australia, more than 5% of hospital admissions are due to unsafe medicines, and a major cause of death and disability.[6]

In 2017, the NSW Government Public Accounts Committee Inquiry into the Management of Health Care Delivery was advised that medication issues "are a very big problem" in Australia, and that the rate of medication issues was particularly high for mental health and geriatric patients (estimated to be up to 40% of all beds).

These facts, demonstrate that there is a chronic need to reduce the high risk on **existing medicines** not just future ones. To fail to introduce boxed warnings on existing medicines is to fail to address existing risk and harm.

Morally the obligation resides with the pharmaceutical company, but failing that the TGA must act to protect consumers through boxed warnings. Simply issuing TGA warnings on the TGA website does not meet these obligations.

What Consumers Want You To Know

> ***"There should be mandatory procedures for doctors and pharmacists to ensure that patients are aware of all serious warnings on medicines."***

Consumers indicated to us that there is a systemic failure to manage unsafe medicines that goes beyond pharmaceutical companies and boxed warnings. They asked us to tell you that:

Informed Consent

> ***"Informed Consent is supposed to be provided to all patients, whereas they are to be educated as to the very real risks, and benefits no matter how large or small. I am disabled 16 years due to unpublished adverse effects of Lipitor. I was a Critical Care RN, prior to taking this drug, for which I never was given anything remotely close to the truth about the adverse effects nor the truth about the minuscule Absolute Risk Reductions of these drugs."***

Consumers repeatedly indicated that they wanted to be involved in their own healthcare decisions. They repeatedly indicated they did not have sufficient information to assess what is right for them.

Not only do consumers want informed consent, they want sufficient information to assess the risks and benefits to them as individuals. Page 30 includes a list of questions consumers want answered prior to taking medicines.

Consumers also expressed to us that there was also insufficient information on the distinction between children, women and men, and pharmacogenomics, for them to make decisions. Also that they are not given product information to make decisions when in hospital.

Pharmacogenomics

> ***"The risk medicine can be for some people who are very sensitive to chemicals and toxins. Most critically the education of doctors and particularly psychiatrists on the risks for people with CYP450 deficiencies."***

96% of consumers wanted pharmacogenomic information included in boxed warnings.

Consumers repeatedly described severe events due to toxicity. What if the medicine was not an issue rather it was the individual's pharmacogenomics?

Idiosyncratic reactions (paradoxical effects) are strongly associated with pharmacogenomic variability in drug metabolizing enzymes in the CYP450 family.

Importantly, recent research studies show that an individual who is a slow or fast metaboliser of certain medicines is four times more likely to become disabled. [7] These findings correlate with many of our consumers' experiences with many reporting brain injuries from the toxicity.

There are now official recommendations on drug choice and dosages, for specific pharmacogenomic types.

The first one was developed by the Pharmacogenetic Working Group of the Royal Dutch Association for the Advancement of Pharmacy (DPWG) and this has been incorporated into the National Dutch electronic prescribing system and so are available to every pharmacist and doctor together with the patient's prescription record.

The second set of recommendations is by the Clinical Pharmacogenetics Implementation Consortium (CPIC). They have reviewed and evaluated the literature using clinical and pharmacokinetic studies on enzyme function, genetic tests, and plasma levels of drugs. The Federal Drug Administration has now included these recommendations where there is sufficient evidence.

The guidelines and recommendations for both DPWG and CPIC can be accessed at https://www.pharmgkb.org/guidelines.

We strongly believe the inclusion of pharmacogenomic recommendations in boxed warnings will enable the individuals to consider themselves, whilst having confidence in the overall safety of the medicine.

Addiction and Withdrawal

> ***"Warnings about withdrawal, and how disabling and damaging it can be, sometimes permanent. Also how to safely come off drugs (not the 4 weeks method) but a gradual dosage over months to years to cause less damage."***

The issue of addiction and withdrawal was one of the most frequently mentioned issues in the comments provided by survey participants.

It is also currently subject to much media attention.

Our survey participants highlighted that the issue of addiction and withdrawal is not a single issue but has a multitude of systemic failures that includes:

- Access and/or consideration of less risky alternatives first,
- The lack of boxed warnings to consumers,
- The lack of an exit strategy before prescribing the addictive medicines, and
- The lack of education of doctors on safe withdrawal methods.

The system is failing them.

Doctor Training and Specialist Clinical Pharmacologists

> ***"Who/where to contact if experiencing these side effects, especially if your care provide dismisses your concerns."***

> ***"Local GP's should not be allowed to prescribe black-boxed medications. Only specialists or within hospitals."***

Consumers almost universally wanted to partner with their doctor on medication decisions. Only 11% of survey participants were warned of adverse reactions.

Doctors are not consistently communicating the risks, and customers experienced an inability to identify or manage adverse events (if any) to the drugs they are prescribing.

Consumers repeatedly stated that they had trouble identifying medical practitioners to help when having severe adverse drug reactions.

Professor Ric Day advised the NSW Government Public Accounts Committee Inquiry into the Management of Health Care Delivery, that there was a desperate need for more specialists and is on record as stating,

"We don't have enough physicians who specialise in the safe and effective use of medicines (clinical pharmacologists) to help patients, other doctors and teach medical students."

As consumers we see increasing specialist clinical pharmacologists, as crucial to driving change through the health system. We want to see a specialist clinical pharmacologist assigned to each hospital district.

Drug Effects

> ***Being repeatedly told it is all in your head by medical professionals does not help recovery. Neither does being given more and more medications for the assumed mental conditions [experienced as a result of the adverse drug reactions].***

Another concern expressed by consumers is the inability of doctors to tell the difference between the drug effects and the person or their medical condition.

The only way to tell if it is the drug effects is for the medication to be safely withdrawn. If the symptoms resolve then it is most likely the medication.

Consumers reported that severe adverse events were automatically dismissed as "their character" of "all in their mind" and not identified as side effects of the medicine.

Similarly, consumers also reported that adverse effects were too often mistakenly interpreted or explained away as a co-morbid condition resulting in the addition of medicines.

This is especially problematic given the significant increased risk of poly-pharmacy with the addition of each medicine.

Areas Of Concern

"Listen to people who actually take the medications and INCLUDE these side effects in the warnings. Doctors don't know… we, the people taking them, know more about these medications."

In preparing this submission, we were struck by how many of the consumer stories, involved medicines for which either the TGA has issued medicine safety updates or for which the FDA now requires the manufacturer to include boxed warnings.

For example, in June 2018, the TGA issued a warning about a number of medicines that can cause severe neuropsychiatric adverse reactions including suicidal behaviour. This included:

- Antidepressants, particularly selective serotonin reuptake inhibitors (SSRIs),
- Certain smoking cessation medications, including varenicline and buproprion (marketed as Champix and Zyban respectively),
- Certain antiepileptics, including sodium valproate, carbamazepine, levetiracetam, phenytoin, lamotrigine, topiramate, pregabalin and gabapentin,
- Isotretinoin (marketed as Roaccutane),
- Atomoxetine (marketed as Strattera and generic brands), and
- Montelukast (marketed as Singulair and generic brands). [8]

This list does not include fluroquinolones that the Food and Drug Administration have recently upgraded their warnings to include risk of neuropsychiatric adverse events.

It is difficult to understand why boxed warnings are not on these products and even more difficult to understand why having issued these warnings the TGA has not included these items in the current proposal.

Response to Questions

Required evidence to support a Boxed Warning

> ***"I want the practice of manufacturers influencing research findings to end."***

We support the proposal for evidence with significant modification.

The proposed evidence requirements do not adequately distinguish between the criteria for listing a medicine (clinical trials) and the potential for risk and/or harm to an individual (individual experience).

Clinical trials generally have strict inclusion criteria and relatively limited numbers of participants. That is they do not consider all types of individuals. They do not consider all the "off target" effects of a medicine, just that the medication works.

We consider the black triangle scheme to signal new products and the boxed warning to signal potential risks to the individual.

We therefore support boxed warnings being based on individual consumer experiences and the trigger for a boxed warnings should be ANY severe event reported on a "Blue Card."

To do otherwise, does not meet the moral and legal obligation of the manufacturer and the regulator, to inform consumers of any and all risk of severe adverse events at the earliest possible point in time.

This would then give the medicine manufacturer the opportunity to have the boxed warning removed or clarified by conducting clinical trials to identify the conditions under which a person is at risk of death or severe harm.

Furthermore, frequency or other statistics is inappropriate due to the severity of the risk and the chronically low reporting of adverse effects (estimated at 5%).

The survey results showed very low awareness of how to report adverse events.

In our opinion this is because the TGA is not communicating with the consumer. The consumer is not on the TGA website. The consumer is with the box of medicine.

The survey results also showed that if a "blue card" was included in the box with the medicine (similar to a product warranty card) or handed out by the pharmacy at the time of the filling the script, the consumer would be more likely to report any adverse event.

As already stated, we also believe the inclusion of Pharmacogenomics (the is to consider the individual) will significantly reducing the potential for harm, but also increase confidence in the overall safety of the medicine itself.

When a Boxed Warning is proposed

> **"The doctors prescribing these drugs need to be more aware that these severe adverse side effects are not that rare, only rarely reported!"**

We support the proposed circumstances with significant modifications.

The events that will trigger a warning are vague. Our survey participants indicated that they consider some events so serious that frequency is irrelevant. These include:

Death

Permanent Disability (of any kind)

Neurological Injury (of any kind)

Neuropsychiatric Side-effects (of any kind)

Brain Damage

Suicide,

Suicide Attempts

Suicidal Ideation

Overdose

Homicidal Ideation

Aggression/Violence,

Addiction

Akathisia

Emotional apathy

Confusion

Withdrawal Syndrome

Neonatal withdrawal syndrome (and associated risks)

Mitochondrial damage

Neuropathy

Tendonitis

Serotonin Syndrome

Endocrine Disruption

Impotence

As the boxed warning is to signal possible risk or harm, for the individual to consider, we believe that frequency is totally inappropriate. Statistics are only relevant if you are not one of them!

Content of the Boxed Warning

> ***"I read the package insert. It did not tell me it would permanently damage my body. I had to go to the FDA website to find that out. All information should be on the package insert."***

We support the proposal.

Boxed Warning and Consumer Medicine Information

> ***"It would have been helpful if the treating Dr went through all the side effects BEFORE starting them."***

We support the proposal.

However, it is imperative that the consumer medicine information is inserted into the medicine box.

When medicine is distributed in hospital (that is in individual dosages) there needs to be a process for communicating boxed warnings.

Format

> ***"They need to be in large print, prominently displayed and doctors and pharmacists need to clearly discuss side effects with patients and their carers. Those that have permanent disabling or deadly side effects should require patients to sign informed consent once the side effects are made known to them by the doctor and pharmacist...."***

We support the proposal with modification.

We would like to see a symbol similar to the black triangle scheme.

A number of our survey participants noted that when they are extremely unwell their capacity to read documents is limited.

The term "warning" does not communicate the severe nature of the risk. The wording should include the words "**Important Safety Warning**".

We would also like to see the boxed warning at least 2pts larger than the text and bolded.

Process requirements

> ***"It doesn't matter where you live, whether in Australia, France, Nigeria, Iceland or the USA -- if a drug carries a warning in one nation, it should carry that same warning in every nation it is distributed, by whatever name or form it is known."***

We do not accept the proposal.

It is totally unacceptable to the consumer that these warnings only be applied prospectively and also totally unacceptable that boxed warnings not be implemented as:

- It does not address the significant existing risk.
- The boxed warning (regarding individual responses) can only truly be established once the item comes to market.
- It will create confusion for the consumer.
- It will create the illusion that a product has no risk off harm on products currently in the market place.
- It will create an erosion of trust in medicine safety.
- It is inconsistent with the warnings already issued.
- It is inconsistent with the practices currently adopted in other countries where warnings are already included and pharmaceutical companies already comply.

Reputable sources should include any and all severe adverse events informed on "blue cards".

Promotional Material

> ***"Warning labels on the outside of the packaging work as a reminder that constant monitoring whilst taking a potentially dangerous medication is important. Many struggle to make a link between the struggles experienced and the medication. Side effects can present at anytime during use for some medications (such as Montelukast)."***

We do not support the outlined options but another.

Your proposal does not expressly address the box in which the medicine comes.

We consider the boxes to be promotional material and as such they should include boxed statements.

The surveyed consumers were adamant that they want the warnings on both the box and the leaflets.

They want the leaflet and the blue card in the box. Where individual dosages are given (for example in hospital) they want the consumer to be provided the leaflet.

As previously stated we also want the warning statement to say "Important Safety Warning" and to contain a symbol similar to the black triangle. Many of our consumers noted that when they were sick they needed clear pronounced warning indicators.

Timelines and implementation

> ***"This needs doing immediately to prevent further harm to people and families."***

We do not support this proposal.

It is totally unacceptable to not apply boxed warnings retrospectively (see above).

Conclusion

> ***"A recent Swiss study of people referred to a community nursing service revealed that 41% had medicine errors, 13% required at least one hospitalization or a medical review and over 60% were preventable. We need doctors who are better-trained and better communication with consumers. And yes boxed warnings. "***

The quality use of medicines demands that the consumer as the foremost stakeholder.

For consumers to experience better health through the quality us of medicines the consumer needs to be considered.

For consumers to benefit from boxed warnings these need to be done from a consumers perspective including:

- Communication by the company of all and any severe events by any individuals
- Communication of individual differences (particularly pharmacogenomics)
- Communication by the doctor
- Communication on the leaflet in the box and the box itself
- Communication with the TGA via a blue box card in the box itself.

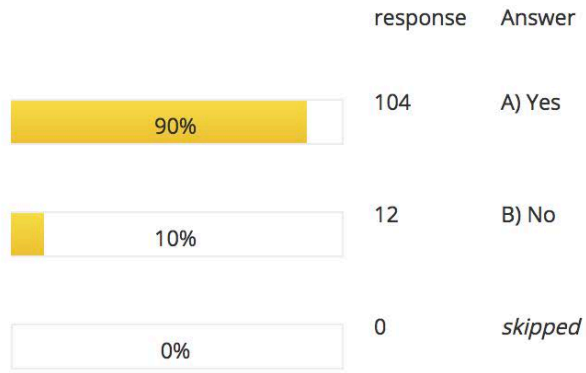
Consumers understand that all medicines have risks and each individual is different. They need stakeholders to help them assess what is right for them and for more training and resources to be available when medicines are unsafe for that individual.

Our supporters would welcome the opportunity to provide any further information or feedback that would assist you in progressing boxed warnings.

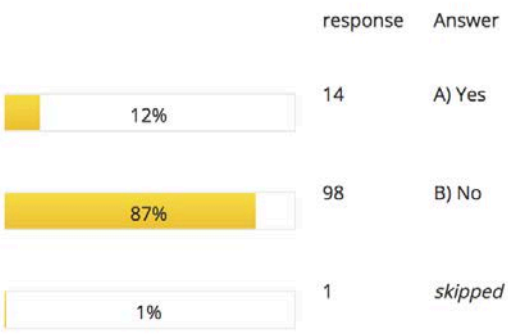
The Wisdom of The Consumer

Consumer Survey

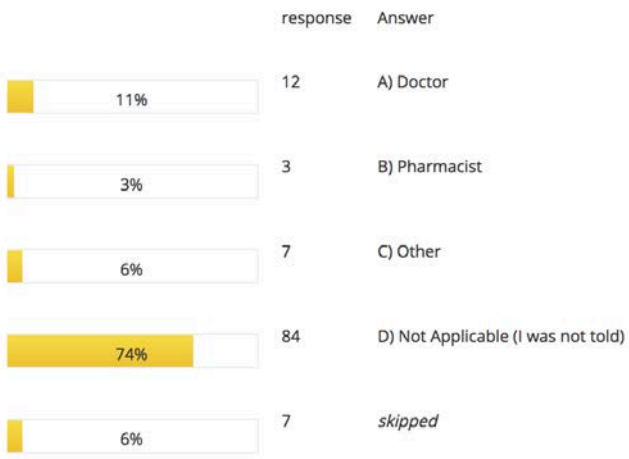
Have you or your loved one been harmed by any medication due to the lack of warnings?



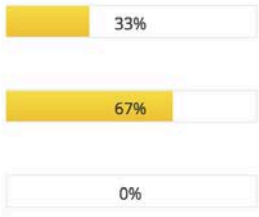
Were you or your loved one told that your medication could cause serious harm before taking it?



If so, who told you or your loved one?

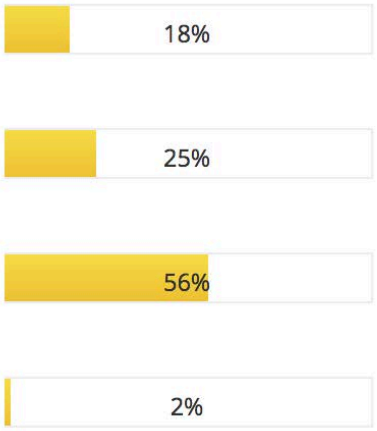


Were you or your loved one given any product information, with details of adverse events, prior to taking the medication?



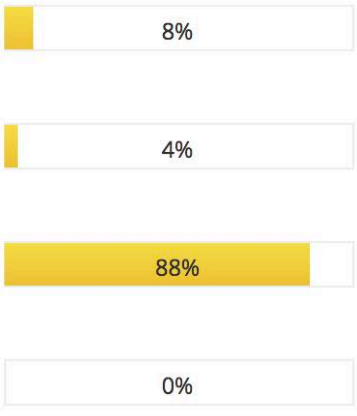
response	Answer
36	A) Yes
73	B) No
0	*skipped*

If so, what product information were you or your loved one given?



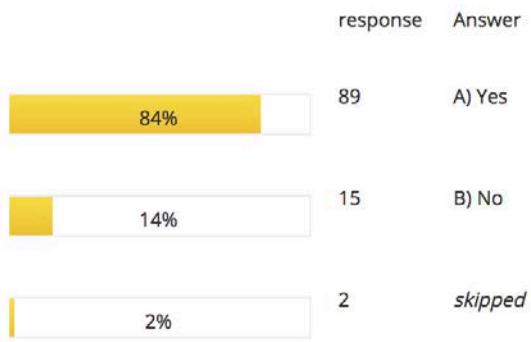
response	Answer
19	A) A print out from the computer
27	B) The leaflet in the box
60	C) Not Applicable (I was not given anything)
2	*skipped*

Where do you think a warning should be placed on the medicine?

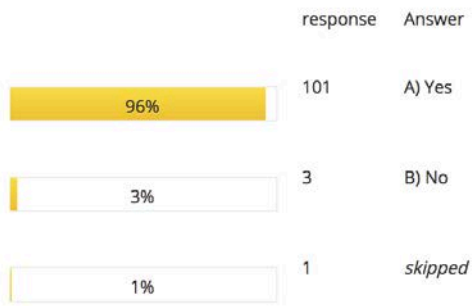


response	Answer
9	A) On the box
4	B) On the top of the pamphlet
94	C) Both
0	*skipped*

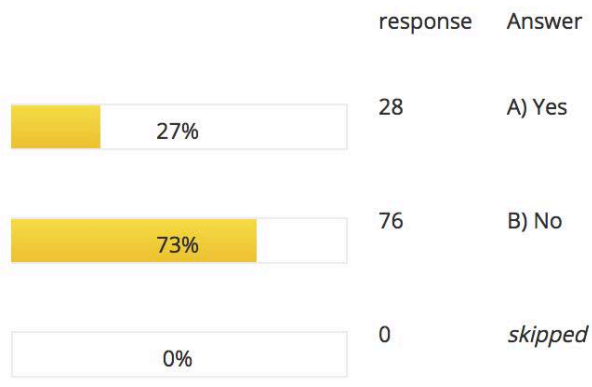
If warnings were only placed on new types of medicines (not existing ones) would this be confusing?



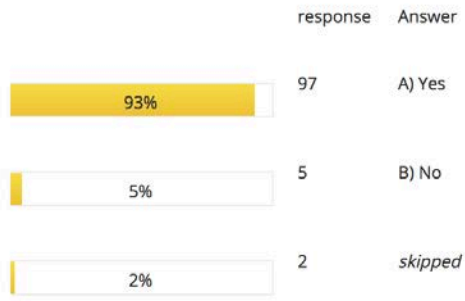
If a medicine was known to be unsuitable for certain genetic types (pharmacogenomics) would you want that to be included in the black box warning?



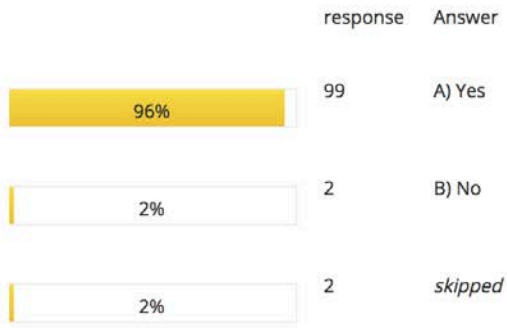
Do you know how to report adverse events to the Therapeutic Goods Administration?



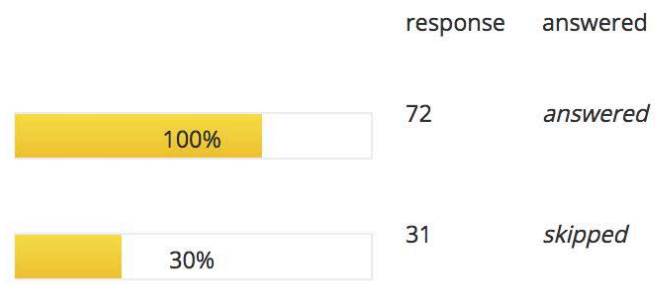
If the form to report adverse events was provided with the medicine would you be more likely to report any adverse events?



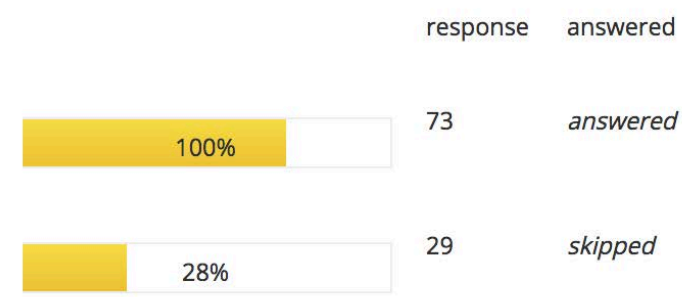
If any medications have these serious adverse effects, do you think it should be mandatory to trigger a Boxed Warning?



Are there any other serious side effects that you want clear Boxed Warnings on?



Is there anything else you want the TGA to know about warnings on medicines?



** The last two questions provided the consumer the opportunity to provide detailed answers. These detailed responses have been included throughout this document.

The Wisdom of The Consumer

Consumer Experiences

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AUSTRALIAN'S FOR SAFE MEDICINES

Let's Talk About Medicines

All medicines have risks. Some medicines are very effective for some people. Some provide little benefit. In other cases, they may even cause harm.

Use these questions to talk to your healthcare provider and community pharmacist about medicines and determine what is right for you.

My Health

1. What are the chances my test results are inaccurate?
2. Do I have a disease or are you concerned about preventing a disease?

My Treatment Options:

3. What lifestyle changes such as diet, sleep, exercise, or stress management could improve my health and my test results?
4. If I do not take this medicine right away will my health get worse?

My Health Benefits:

5. If I take this medicine how will it improve my health?
6. What is the success rate of this medicine?

My Health Risks:

7. What side effects could I experience if I take this medicine?
8. If this medicine is not right for me how easy is it to stop it?
9. If I stop this medicine will I experience any permanent side effects?
10. Is this medicine compatible with my other supplements or medicines?

My Genetics:

11. Do I have the enzymes to metabolize and eliminate this medicine?

My Health Review

12. If I take this medicine, when will we talk about how I am going on it?

Australians For Safe Medicines
www.safemedicines.com.au

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