

Australian Government
Department of Health
Therapeutic Goods
Administration
Submission



**Asthma
Australia**

Health policy and positions

31/08/18

Draft Boxed Warning guidance: Public consultation

Required evidence to support a Boxed Warning

Q1: Do you support the proposal for evidence?

Yes

Q2: Do you envisage any difficulties with the proposed evidence requirements?

No

When a Boxed Warning is proposed

Q4: Do you support the proposed circumstances?

Yes

Q5: Do you envisage any difficulties with the circumstances under which a Boxed Warning is proposed?

Content of the Boxed Warning in the PI

Q7: Do you support the proposal?

Yes

Content and Format of the Boxed Warning in the CMI

Q9: Do you support the proposal?

Yes

Format of the Boxed Warning in the PI

Q11: Do you support the proposal?

Yes

Process requirements

Q14: Do you support the proposal?

Yes

Promotional material

Q17: Which of the above options do you support?

Option 2

Q18: No suggestions

Timelines and implementation

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Q19: Do you support the proposal?

c) with modification

An audit should be done on medicines currently in market that would qualify for boxed warnings and these medicines attract boxed warnings. If too onerous, perhaps this measure could be phased.

Q20: Do you envisage any difficulties with the proposed prospective implementation?

Not so much difficulties, more risks associated with not including medicines who might qualify for boxed warnings, who continue in market without them and potentially are used in a risky way by prescribers and consumers.

Q21: Are there other modifications or additions to the proposal you would like to make?

In the case that prescribers won't read PIs before prescribing medicines and consumers will discover the boxed warnings on first use, when self-administering or administering for a dependent which might be the first time they have had a chance to acknowledge or consider the risk of the medicine, consumers are not getting best benefit from this system. This is not sufficient and can be very costly, inconvenient and risky for people. Asthma Australia would encourage TGA to evaluate the effectiveness of the boxed warning protocol after implementation, paying particular attention to prescriber behaviour change and consumer impact.

As has recently been highlighted in media, medication prescription is the third most important public health risk after heart disease and cancer¹. Boxed warnings should not only make prescribing easier for prescribers, they also have the potential to save consumers' lives and should be used judiciously to this effect. Retrospective implementation should be considered as should be considerations made around the best way to introduce them and how they might be used by a patient to enable their agency in treatment decision making.

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¹ Gøtzsche PC. Deadly Medicines and Organised Crime: How big pharma has corrupted health care. London: Radcliffe Publishing; 2013