August 28, 2018

Comments on the TGA proposed guidance for the use of Boxed Warnings for prescription medicines.

Q1. (a) Yes, we support the proposal for evidence.

Currently calls to the NSW Poisons Information Centre regarding therapeutic errors and adverse reactions to medications with moderate to severe symptoms are reported to the TGA monthly (average 35/month). Analysis of national Poisons Centre data from 2015 showed 2658 calls regarding adverse reactions and 29,739 calls regarding medication errors. The large number of annual calls can be analysed to provide further insight into adverse reactions, toxicity and medication errors for specific medications if required. The minimum data set used by the NSW Poisons Information Centre can be expanded to gather extra information on adverse reactions and toxicity for prospective studies on agents of interest.

Q2. The only difficulties we envisage regarding the evidence requirements would be the time frame in which the evidence is required being sufficient to allow for adequate data analysis, and the cost associated with extraction and analysis of the data.

Q3. If detailed data analysis for evidence is requested by the TGA, then the NSW Poisons Information Centre is appropriately reimbursed.

Q4. (c) Yes we support the proposed circumstances for requirement of a Boxed Warning, with the amendment of the second point:

- A serious adverse reaction ***or poisoning risk*** is identified that can be prevented or reduced in frequency or severity by appropriate use of the drug, encompassing:

Q5. No, we do not envisage any difficulties with the circumstances under which a Boxed Warning is proposed.

Q6. n/a

Q7. (a) Yes, we support the proposal for content of the Boxed Warnings.

Q8. n/a

Q9. (c) Yes, we support the proposal for content and format of Boxed Warnings in the CMI, with the amendment of point 3

- In language that will be easily understood by patients, ***as confirmed by consumer group testing***

As the information in Boxed Warnings is particularly important it is vital that it is tested to confirm consumers understand the message. CMIs are not currently required to undergo consumer testing to confirm readability.

Q10. No, there are no other modifications or additions to the proposal for content and format of Boxed Warnings we would like to make.

Q11. Yes, we support the proposed format of Boxed Warnings in the PI.

Q12. n/a

Q13. No other modifications proposed

Q14. Yes, we support the proposal for process requirements of Boxed Warnings.

Q15. No, we do not envisage any difficulties with the proposed process.

Q16. There are no other modifications to the proposal for process we would like to make.

Q17. (a) We support Option 1 • All promotional material must include the Boxed Warning in full.

Q18. Boxed warnings in various media forms should be of appropriate font size relative to the rest of the promotional material to enable the viewer to read the contents of the warning with ease.

Q19. (c) We support the proposed timeline for implementation of Boxed Warnings with modification to include a phase in time period (e.g. 3 years) for the guidelines to apply retrospectively to all existing Boxed Warnings as well as new applications.

Q20. No we do not envisage any difficulties with the proposed prospective implementation.

Q21. There are no other modifications or additions to the proposal we would like to make.

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