Dear Sir/Madam

Re: NSAIDS for oral use: proposed additional advisory statements

The Pharmacy Guild of Australia welcomes the opportunity to comment on the proposed advisory statements for oral Non-Steroidal-Anti-Inflammatory Drugs NSAIDs prepared by the Therapeutic Goods Administration (TGA).

The Guild supports the following proposed statements, as amendments to the Required Advisory Statements for Medicine and Labelling (RASML) for oral medicines containing flurbiprofen, ibuprofen, ketoprofen, mefenamic acid or naproxen:

- Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive or prolonged use can be harmful and increase the risk of heart attack or stroke.

The Guild also supports the following proposed RASML amendment for oral medicines containing diclofenac:

- Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive or prolonged use can be harmful and increase the risk of heart attack, stroke or liver damage.

Additional Comments

Whilst the Guild supports these RASML amendments, we wish to highlight our view that medicine advisory statements complement the role of healthcare professionals and cannot and should not be seen as a substitute to a consumer seeking professional advice on the use of medicines.

We note that when RASML No.2 comes into effect in December 2015, these medicines will be required to display a total of nine RASMLs on their packaging. This is a large number of medicines.
specific statements (several of them have potential serious consequences if overlooked by a consumer) and we therefore question the suitability of having some of these medicines (ibuprofen in particular) exempt from scheduling where they can be purchased from a general retail setting with no access to healthcare professional advice.

As stated in our response to the review of cardiovascular safety of NSAIDs and safety review of diclofenac submitted November 2014, the use of warning statements does not replace the advice provided by a healthcare professional and the inclusion of such a large number of statements is particularly risky for people with poor health literacy or those from culturally and linguistically diverse backgrounds. There is also a risk that consumers may experience "warning label fatigue" and not take heed of the multitude of different warnings. Furthermore, there is a health risk to consumers who perceive NSAIDs to be 'safe' because they are available in a general retail setting.

The Guild also feels that there sometimes appears to be an inconsistency between relevant groups within the TGA that consider the scheduling of a medicine and those that consider labelling requirements.

We believe that there should be greater consistency between RASML requirements and scheduling classifications for medicines. Consideration should also be given to imposing a 'cap' on the number of RASMLs that can apply to a medicine exempt from scheduling before consideration given to removing this exemption. This would ensure medicines deemed to be of such high risk that they require multiple advisory statements are only available from outlets where consumers have access to advice from healthcare professionals so that the suitability of the medicine for a consumer can be determined and appropriate advice provided.