CONSULTATION: NON-STEROIDAL ANTI-INFLAMMATORY DRUGS FOR ORAL USE: PROPOSED ADDITIONAL ADVISORY STATEMENTS FOR MEDICINES

NPS MedicineWise
March 2015
Introduction

Thank you for the opportunity to respond to the proposed advisory statements for oral non-steroidal anti-inflammatory medicines consultation.

NPS MedicineWise is an independent, evidence-based, not-for-profit, national organisation that has been funded by the Australian Government since 1998 to promote quality use of medicines and, more recently, medical tests.

As you may be aware, we improve the way medicines and other medical technologies are prescribed and used in practice. We do this through behaviour change interventions, evidence-based information to support decision making and targeted health communications campaigns. As such, we are well placed to respond to this consultation, given our unique understanding of the quality use of medicines landscape in Australia and our experience in health professional and consumer education.

We welcome this proposal by the Therapeutic Goods Association (TGA) and the timely response to recently released evidence about the risks and possible side effects of oral non steroidal anti-inflammatory medicines. We note the agility of the TGA’s response demonstrates the relevance of your ongoing role in regulating therapeutic goods in Australia.

As the TGA is well aware, the content of labels on medicines can have a significant impact on the quality and safety of medicine use. NPS MedicineWise runs education campaigns targeting health professionals and consumers about how to read and understand the labels on medicines and there is further detail available below.

Our submission addresses the proposed advisory statements and the associated health literacy issues as well as other significant concerns such as the need for pharmacovigilance to monitor associated adverse effects and impact on other pain relievers and the importance of education for consumers and staff at the point of supply.

NPS MedicineWise has a strong interest in the implementation of these labelling changes. We believe there may be opportunity to further enhance the safety and quality use of these changes through our provision of education and resources to health professionals, consumers and grocery retailers when finalised and as appropriate.

NPS MedicineWise looks forward to the outcomes of this consultation in determining the wording of these advisory statements and the associated issues.

NPS MedicineWise programs

NPS MedicineWise develops and delivers educational programs, tools and resources to health practitioners including general practitioners, pharmacists, nurses and specialists to improve the way medicines and medical tests are used in practice. We also provide national consumer campaigns which trigger and sustain long term measurable behaviour change.

Our campaigns focus on empowering the consumer to be more informed about medicines: knowing the active ingredient, understand the questions to ask health professionals, and participate in health care decision making. One aspect has been supporting people to know where to find information on medicine labels as this is key to consumer safety.
Improving pain management is a key interest and we are launching a program designed to improve the management of chronic non-cancer pain. Our national program is launching in June 2015. Although our program is not specific to the use of non-steroidal anti-inflammatory medicines (NSAIDs), it does provide consumers with tools to better manage their symptoms and communicate their pain and concerns about their treatment. The program also provides health professionals with tools and resources to improve pain management in primary care.

NPS MedicineWise is also involved in educating staff at the point of supply, whether this is in a pharmacy or the supermarket setting. We recently partnered with the Australian Self Medication Industry (ASMI) and major grocery retailers (Woolworths, Coles, Metcash) on our ‘QUM supermarket’ project which focuses on ways to enhance QUM in self-selection outlets. The outcome of this project was principles and guidelines for retailers to translate into new healthcare models in store.

The proposed advisory statements

The labels of oral medicines containing flurbiprofen, ibuprofen, mefanamic acid or naproxen will require an advisory statement:

*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 increase the risk of heart attack or stroke.*

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 increase the risk of heart attack, stroke or liver damage.*

NPS MedicineWise recommended alternative wording options

Prolonged use can be harmful and increase the risk of heart attack or stroke. Do not exceed the recommended dose. In the absence of medical advice avoid use for more than 3 days.

Prolonged use can be harmful and increase the risk of heart attack, stroke or liver damage. Do not exceed the recommended dose. In the absence of medical advice avoid use for more than 3 days.

OR

Do not exceed the recommended dose. Ask your doctor before you take this medication for more than a few days. Prolonged use can be harmful and increase the risk of heart attack or stroke.

Do not exceed the recommended dose. Ask your doctor before you take this medication for more than a few days. Prolonged use can be harmful and increase the risk of heart attack or stroke or liver damage.
NPS MedicineWise is concerned there may be a health literacy issue in understanding the meaning of ‘excessive or prolonged use’. We believe three syllable words add to the degree of difficulty in comprehension, particularly for culturally and linguistically diverse communities and people with low literacy.

In the context of self-management of pain, unintentional overdose of analgesics has been clearly documented. For example, in a study of paracetamol induced acute liver failure, unintentional overdose accounted for 50% of the cases. The rate of unintentional overdose was estimated to be 31% in Australia (Larson, AM 2005). It is likely that ongoing or worsening pain may lead people to override labelling instructions, as the need to relieve the pain dominates. In this context, what constitutes ‘a few days’ loses significance. We therefore recommend clearly specifying the time period which is intended by the term ‘a few days’.

The use of the phrase ‘unless a doctor has told you to’ is not in line with the patient centred approach which is becoming the foundation of primary care. Efforts to improve labelling need to facilitate communication between the consumer and health professional to improve health outcomes and empower the consumer to be active in making the right decisions with regard to their medication choices. Directing the consumer to ‘ask their doctor’ opens lines of communication where the proposed advisory statement does not.

**Pharmacovigilance**

Pharmacovigilance will be critical to ensure there are not unintended consequences from these labelling changes. There is a need to assess three main areas where change might occur when these labelling changes are instigated:

- Changes in the incidence of heart disease, stroke and liver damage associated with NSAID use
- The impact of labelling changes on patterns of opioid prescribing

These labelling changes may lead to more referrals to doctors as those at greatest risk from NSAIDs are those with the highest co-morbidities such as osteoarthritis.

- The impact of labelling changes on patterns of codeine use

It will also be necessary to monitor over the counter use of other analgesics as this may result in different patterns of product choices for longer term pain relief.

Monitoring changes in these three areas will provide information and feedback on these labelling changes which will enable further changes to be made as is necessary to improve consumer safety.

**Education**

To complement the proposed labelling changes, we recommend provision of further information for consumers at the point of supply. We believe this would improve the safety and quality use of these medicines. The content of this education should address the potential reasons and drivers for excessive and prolonged use and should include: perception of safety due to the widespread availability, potential for increased risk of stroke, heart attack or liver damage, and avoiding co-administration of an over-the-counter NSAID with a prescribed NSAID.

Education should enable consumers to be aware of the reasons behind labelling changes and the consequences of taking these medicines outside of the labelling requirements. Consumers may also benefit from knowing about other choices in pain relief such as non-pharmacological interventions, paracetamol alone and topical NSAIDs.
Conclusion

Because of the widespread availability of NSAIDS, NPS MedicineWise believes the labelling changes must take into account the needs of all potential users in the community and support comprehension at minimal literacy levels. The use of words with three syllables does not meet this criterion. We also believe there needs to be more direct instruction defining the phrase ‘a few days’ as pain often overrides interpretation of an undefined length of time. Other significant issues for consideration include the need for pharmacovigilance to monitor the safety and impact of these labelling changes as well as the provision of education to improve consumer safety with regard to NSAID administration.

NPS MedicineWise supports the need for education to complement the proposed labelling changes. Education will assist consumers to understand and comply with dosing instructions. Should you decide to proceed with an education campaign, we are well placed to provide programs to those affected by these labelling changes. This education not only involves health professionals and consumers but also extends to supermarket retailers.

Reference: