News room

- News & public notices
- Consultations & reviews
  - Open consultations & reviews
  - Closed consultations & reviews
  - Consultation forecast
  - Consultation principles for therapeutic goods regulatory reforms
- Events, training & presentations

Consultation: Review of cardiovascular safety of non-steroidal anti-inflammatory drugs and Safety review of diclofenac

7 October 2014

Closing date: 6 November 2014

Invitation to comment

The TGA is seeking comments from interested parties following a Review of cardiovascular safety of non-steroidal anti-inflammatory drugs (NSAIDs) and a Safety review of diclofenac.

These reviews identified some risks associated with over-the-counter (OTC) NSAIDs and the TGA has put forward four alternative options for strategies to mitigate these risks.

Consultation documents

Consultation: Review of cardiovascular safety of non-steroidal anti-inflammatory drugs (NSAIDs) and a Safety review of diclofenac - Summary and issues document (pdf,237kb)

How to access a pdf or Word document

Consultation: Review of cardiovascular safety of non-steroidal anti-inflammatory drugs (NSAIDs) and a Safety review of diclofenac - Summary and issues document (Microsoft Word,111kb)

Timetable

Documents released for consultation on **Tuesday 7 October 2014**.

Interested parties should respond by close of business **Thursday 6 November 2014**.

Feedback will be released following consideration of submissions. (See 'What will happen').

About the consultation

The Review of cardiovascular safety of non-steroidal anti-inflammatory drugs and Safety review of diclofenac can be found on the TGA website.

The TGA's overall conclusions, based on these two reviews of the risks associated with the use the NSAIDs available in Australia, are as follows.

- All eight NSAIDs - celecoxib, etoricoxib, indomethacin, meloxicam, piroxicam, diclofenac, ibuprofen and naproxen - are associated with significantly increased risks of stroke, heart attack or other cardiovascular events and they should be used with caution in patients with predisposing cardiovascular risk factors.
- There is a need for more awareness among health professionals and patients regarding the cardiovascular and hepatotoxicity risks associated with NSAIDs. While these risks and necessary precautions are described in the current Product Information (PI) documents, there is, in some cases, a need for greater consistency in the wording used and for prescribers to be made more aware of the importance of assessment of risks in each individual patient, the increased risk of cardiovascular events (especially in patients with prior cardiovascular disease or risk factors) and the need for periodic assessment to detect any signs or symptoms indicating cardiovascular events associated with NSAID treatment.
- These medicines provide effective pain relief when used according to the label, at recommended doses and for short durations of time. However, there is a need to increase consumer awareness through additional and stronger label warnings about the cardiovascular risks associated with these medicines, and the need for patients with cardiovascular disease or risk factors to consult a health professional before using them. Consumers also need to be made more aware of the need to limit the dose and duration of treatment in accordance with the package instructions unless otherwise advised by a health professional.

Content of submissions

Submissions may address any, or all, of the alternative options offered in this document or other identified issues.

There are four alternative options being put forward in this consultation document. The options put forward focus specifically on strategies to mitigate the risks associated with OTC NSAIDs.

Any action undertaken is designed to increase awareness among consumers and health professionals of the risks associated with NSAID use and therefore decrease the number of adverse events. In this context, option 1 is not considered to be a viable option.

The four proposed options are:

- **Option 1 - Status quo**
  - No changes are made to labels; nor are any communication activities undertaken to raise health professional and consumer awareness.
- **Option 2 - Non-regulatory**
  - No changes are made to labelling and no changes are made to the scheduling. Instead TGA uses existing communications channels and publications and also works with stakeholders such as NPS MedicineWise to raise awareness and educate health professionals and consumers on the risks associated with the use of NSAIDs.
- **Option 3 - Regulatory**
  - **Label changes**
    - TGA requires sponsors of pharmacist-only, pharmacy-only and unscheduled OTC NSAIDs

to update their labelling information (and/or CMI, as applicable) or are required to have a CMI supplied with the product as a package insert.

- The label changes could be imposed through:
  - an update to the Required Advisory Statements for Medicine Labels (RASML) with the additional required advisory statements
  - a change of condition of registration under Section 28 of the Act.

- **Re-scheduling OTC NSAIDs**
  - All unscheduled and pharmacy-only OTC NSAIDs could be considered for re-scheduling to be pharmacist-only to ensure the intervention of pharmacist at the time of supply. If rescheduled, these products would still require changes to their labelling.

- **Option 4 - Combination of regulatory and non-regulatory activities**
  - TGA requires sponsors of pharmacist-only, pharmacy-only and unscheduled OTC NSAIDs to update their labelling information as outlined in Option 3. Labelling updates would be complemented by communications activities undertaken by the TGA in collaboration with existing stakeholders.

Submissions may address any, or all, of the options listed above. In addition, submissions might include:

- suggested improvements or alternatives to the options
- whether or not you support the specific or parts of options or a combination of options. If you do not support the options you may make suggestions for an alternative that is acceptable to you
- an assessment of how the proposed options will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify the direct and indirect costs and benefits
- your views in relation to other benefits and costs that you consider relevant.

Any submissions will inform the final decision which will be taken by the TGA.

How to respond

All submissions should be accompanied by a TGA submission cover sheet. Submissions must include full personal or organisational contact details (including address, telephone number and email).

Submission cover sheet: Consultation: Review of cardiovascular safety of non-steroidal anti-inflammatory drugs (NSAIDs) and a Safety review of diclofenac - Summary and issues document (Microsoft Word,36kb)

Electronic submissions are preferred and should be emailed to Dr Jane Cook at si.coordinator@tga.gov.au. Please include 'Review of Cardiovascular Safety of Non-steroidal Anti-inflammatory Drugs and Safety Review of Diclofenac' in the subject line of the email.

Alternatively, hardcopy submissions may be mailed to:

Dr Jane Cook
Office of Product Review
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

What will happen

All submissions will be placed on the TGA Internet site unless marked confidential or indicated otherwise in the submission coversheet (see Privacy information).

Submissions will be reviewed and considered by the TGA and any updates on proposed actions will

be provided through the TGA internet site.

Privacy information

- The TGA collects your personal information in this submission in order to:
  - contact you if the TGA wants to seek clarification of issues raised in your submission or to check whether you consent to certain information that you have provided being made publicly available.
  - help provide context about your submission (e.g. to determine whether you are an individual or a director of a company or representing an interest group).
- The TGA will disclose your name and (if applicable) your designation/work title on the TGA Internet site (i.e. make this information publicly available) if you consent to the publication of your name on the TGA Internet site (please complete the cover sheet).
- Any text within the body of your submission that you want to remain confidential should be clearly marked 'IN CONFIDENCE'.
- Please do not include personal information about other individuals in the body of your submission. Personal information in this context means information or an opinion about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

Enquiries

Any questions relating to submissions should be directed to the Head, Office of Product Review, Dr Jane Cook by email to si.coordinator@tga.gov.au or by telephone to 02 6232 8188.

Top of page

Content last updated: Tuesday, 7 October 2014

Content last reviewed: Tuesday, 7 October 2014

Web page last updated: Tuesday, 7 October 2014

URL: http://www.tga.gov.au/newsroom/consult-nsaid-diclofenac-141007.htm