Re: Consultation: Non-steroidal anti-inflammatory drugs (NSAIDs) for oral use - Proposed advisory statements for medicines

Dear Sir/Madam

Pfizer would like to thank the TGA for the opportunity to comment on the proposed advisory statements for oral non-steroidal anti-inflammatory drugs (NSAIDs) for medicines for oral administration. The response below only refers to the OTC NSAIDs products marketed by Pfizer.

Proposed statements:
For oral medicines containing flurbiprofen, ibuprofen, ketoprofen, mefenamic acid or naproxen:

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

Pfizer does not object to the inclusion of the proposed statements in the next update of Required Advisory Statements for Medicine Labels (RASML), however, there are two issues noted below where Pfizer seeks clarification. The requirement for any additional label changes will be dependent on the outcome of these queries, namely the suitability of Pfizer’s current cardiovascular warning statement, and the impact on paediatric preparations.

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CARDIOVASCULAR WARNING STATEMENT

The following cardiovascular warning statement is included on all adult Advil presentations currently marketed, and in the case of Ponstan (AUST R 14388), has been proposed in a recent label variation application:

"Long term continuous use may increase the risk of heart attack or stroke"

This wording is provided in addition to the existing RASML warning statements relating to limiting the dose and duration of use, namely:

"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 use can be harmful."

It is Pfizer's position that this warning statement effectively and clearly conveys the same message as the proposed cardiovascular warning statement subject to the current consultation and equally addresses the concerns raised in the review. Pfizer seeks TGA's confirmation that this statement is considered be equivalent to the proposed advisory statement and would be considered to be compliant should the proposed cardiovascular warning statement be included in RASML.

Pfizer proposes that the cardiovascular statement already included on Pfizer's OTC NSAIDs be included in RASML as an alternative advisory statement. Formal written verification of compliance from TGA might otherwise be an alternate means of achieving this to ensure compliance is confirmed both now, and into the future.

PAEDIATRIC PREPARATIONS

It is unclear whether the proposed cardiovascular risk warning statement is intended for paediatric products.

In 2008, Pfizer was provided the following advice by the TGA (full email provided as attachment):

"Delete the warning long term continuous use may increase the risk of heart attack or stroke".

In the overall context of this product presentation, it is considered that such a statement is inappropriate, inaccurate and may cause unnecessary alarm to parents and caregivers. It is also not required by RASML/SUSDP/ARGOM. Given that is not included in other OTC ibuprofen product labels for infants /children's use, it may even a disadvantage your product and create consumer confusion regarding the safety of different children's ibuprofen brands".

Therefore Pfizer seeks clarification as to whether the proposed cardiovascular warning statements are intended to be applied to paediatric products given TGA's previous position on this.

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Again, Pfizer appreciates the approach taken by TGA in reviewing this matter, and look forward a response on the issues raised.

Yours sincerely

Pamela Quane
Associate Regulatory Director