

12 July 2013

OTC Medicines Regulatory Process
Review
Therapeutic Goods Association
PO Box 100
Woden
ACT 2606
Australia

CONSULTATION RESPONSE

OTC MEDICINE MONOGRAPHS FOR PARACETAMOL, ASPIRIN & IBUPROFEN Version 1.0, July 2013

Dear Sir / Madam

Introduction

The New Zealand Self Medication Industry (NZSMI) is the representative trade organisation for the major "*over the counter*" (OTC) medicine sponsor companies within New Zealand.

We appreciate the opportunity to make comment on the consultation paper and hope our comments are taken in a constructive manner to assist in developing the final document.

We are willing to support our comments verbally if required and meet with representatives of TGA or Medsafe if appropriate.

Yours faithfully

EXECUTIVE SUMMARY

- NZSMI still questions the benefit of the monograph system from a New Zealand perspective. With the small number of monographs offered, we are concerned at the small number of applications that will use this route and question whether this minimal number requires a separate registration process. If this number of monographs is to be expanded, the application route is likely to be used more often, especially if the cost is reflective of the time the agency spends reviewing the data which we envisage will be lower than the current evaluation route takes.
- From a New Zealand perspective NZSMI sees little financial benefit and speed to market using this process. Reducing the timeline by approximately four weeks is a minor incentive for sponsors.
- NZSMI is also concerned that the consultation only impacts monographs that are to be utilised in Australia and that New Zealand, at this stage, has been excluded from the process. We would have thought with ANZTPA approaching it would have been an ideal time to trial monographs in both countries simultaneously.
- NZSMI believes that if the monograph system for actives such as paracetamol, ibuprofen and aspirin are to be utilised then it would be of real value if the active could be maintained using the monograph system throughout its lifecycle.
- If it is to proceed, NZSMI is overall supportive of the specific OTC monograph documents for the actives- paracetamol, ibuprofen and aspirin.

OTHER SPECIFIC COMMENTS

When ANZTPA is fully consummated, it will be critical that dosage forms that are currently allowed in New Zealand are included in the OTC medicine monograph. For example, aspirin 75mg needs to be included in the aspirin monograph. Similarly 250mg/5ml suspension as a dosage needs to be included in the OTC medicine monograph for paracetamol. Ibuprofen has similar examples where there are unique New Zealand dosages which are not available in Australia.

We are supportive of the labelling initiative that allows for age bands rather than the requirement where every single age has to have a weight and dosage line allocated to it. Currently there are some issues with Medsafe on this layout principle and it is essential that uniformity is agreed between the TGA and Medsafe now, prior to ANZTPA being introduced.

CONCLUSION

Although as we have stated earlier, we believe that the monograph system will not be used widely and therefore have questioned its introduction. If it is to be introduced, the monograph must be able to be used for maintenance of the product as well as registration at the N2 application stage.