Consumers
Health Forum
of Australia

7 November 2012

OTC Medicines Regulatory Process
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam

Submission to consultation on over-the-counter medicines business process reform

The Consumers Health Forum of Australia (CHF) welcomes the opportunity to provide a submission to the Therapeutic Goods Administration (TGA) and Medsafe Consultation Paper *Over-the-counter (OTC) medicines business process reform*, as part of the OTC Business Review Project (the Project).

CHF is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

The issues outlined in the Paper are primarily a matter for the medicines industry; however, the impact on consumers as the end-users of therapeutic goods should be considered in any significant regulatory reforms. CHF has provided a number of recommendations on a range of issues discussed in the Consultation Paper. CHF also seeks further information about what public awareness activities are planned to support these reforms.

Risk Categorisation Framework
The proposed Risk Categorisation Framework outlined in the document has direct implications on consumer safety. The proposed categories (both for new and changed medicine applications) appear to be well-considered in terms of the characteristics of the medicine, and their potential risks to the community. However, to ensure that there is adequate consumer protection, CHF recommends that these categories be reviewed within a reasonable timeframe to ensure they are appropriate.

Medicine Monographs
CHF supports the concept of developing OTC medicine monographs (OMMs) for medicines with well-characterised active ingredients. The OMMs will expedite the assessment process for the TGA and MedSafe, allowing them to review an abbreviated, rather than a full, data package with the sponsor's application. However, CHF recommends that there is increased monitoring of sponsor compliance with evidence requirements, at least in the initial period after implementation, to ensure that sponsors actually possess the full data package as required.

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Umbrella branding
CHF welcomes the acknowledgement that 'umbrella branding' poses a higher risk to consumers. Umbrella branding may result in look-alike and sound-alike medicines that could cause confusion for consumers, which has the potential to impact on consumer safety by contributing to self-medication errors. This is reflected in the proposed risk categorisation framework for new medicine applications and changes, in which products with umbrella branding require a higher level of assessment.

The TGA's current labelling and packaging review proposed changes to reduce the risk of consumer confusion and medication errors resulting from look-alike sound alike names, look-alike packaging and look-alike branding. CHF recommends that the outcomes from the TGA's labelling and packaging review should be considered as part of this Consultation.

Public awareness
The Paper notes that implementation of the Project's proposals in Australia will 'improve publically available information about the regulation of OTC medicines'. However, the Paper provides no further details on how the availability of information will be improved. CHF therefore would welcome further information about how this will be achieved.

CHF awaits the outcomes of the Consultation with interest. If you would like to discuss this submission in more detail, please contact CHF Project Officer, Carlo Malaca.

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CHIEF EXECUTIVE OFFICER

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