Consultation submission cover sheet

This form accompanies a submission on:

The document 'Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants)'	
Name and designation	Mr Carlo Malaca
Company/organisation name and address	Consumers Health Forum of Australia 11 National Circuit, Barton, ACT, 2600.
Contact phone number	02 6273 5444

I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)*	☐ Yes ☒ No
I would like my name to be removed from all documents prior to publication and not be included within the list of submissions on the TGA website.	☐ Yes ☒ No

It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, a: *(tick all that apply)*

Business in the therapeutics industry *(please tick sector):*

☐ Prescription medicines ☐ Complementary medicines ☐ OTC medicines

☐ Medical devices ☐ Blood, tissues, biological ☒ Other

☐ Sole trader ☐ Business with employees

☐ Importer ☐ Manufacturer ☐ Supplier ☐ Industry organisation

☐ Government ☐ Researcher ☐ Professional body

☒ Consumer organisation ☐ Institution (e.g. university, hospital)

☐ Regulatory affairs consultant ☐ Laboratory professional

☐ Health professional – *please indicate type of practice*:

☐ Other - *please specify*:

It would help in the analysis of stakeholder comments if you provide the information requested below.

Comments

An assessment of how the proposed change 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 these costs and benefits.
See Submission
Whether or not you support the revised Evidence Requirements. If not supported, please provide reasons why.
See Submission
Any additional information on issues not asked in the above questions. If your comments relate to specific parts of the document please provide the page number and reference.
See Submission

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Consumers
Health Forum
of Australia

17 October 2012

Office of Complementary Medicine
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam

Submission to the Consultation on Version 2 of the draft document *Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants)*

The Consumers Health Forum of Australia (CHF) welcomes the opportunity to provide a submission to the Consultation on Version 2 of the draft document *Evidence required to support indications for Listed medicines (excluding sunscreens and disinfectants*). CHF also provided a submission to the TGA's Consultation on the original version of this document, in May 2012.

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.

Overall, CHF is disappointed that the TGA has not maintained the strength and clarity of the evidentiary requirements contained in the original version of the document, and has significant concerns about the removal of the requirement for an expert report on the evidence for a product to be provided by sponsors in their application to list a medicine.

CHF requests that the TGA also address the issues surrounding the lack of public awareness of the different requirements for Listed and Registered products, and the low rate of compliance of Listed medicines with evidence requirements.

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

Yours sincerely

Carol Bennett
CHIEF EXECUTIVE OFFICER

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Consumers
Health Forum
of Australia

Submission to the Consultation on Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants)

October 2012

Submission to the Consultation on Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants)

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Introduction

The Consumers Health Forum of Australia (CHF) welcomes the opportunity to provide a submission to the Therapeutic Goods Administration (TGA) Consultation on the August 2012 version of the draft document *Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants).*

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.

CHF has a strong interest in the regulation of, and evidence requirements for, Listed medicines. We have previously raised concerns about regulatory and evidentiary requirements related to Listed medicines in earlier reviews and consultation processes including but not limited to, the submission we provided in May 2012 to the original version of the draft Consultation document *Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants).*[1]

CHF notes that the strength and clarity of the requirements outlined in the original version of the document has not been maintained in Version 2 of the draft document. Consumers should have confidence that the products they are purchasing are safe and efficacious and comply with quality and established regulatory standards. While many sponsors do adhere to such standards, it is clear from the high rates of non-compliance with evidence requirements observed by the TGA in post-market monitoring review activities[2,3] that a large percentage of Listed products are not compliant.

CHF understands that Listed medicines are considered lower risk and that the Listed process provides consumers with expedited access to these medicines. However, there must a balance between providing expedited access to therapeutic goods and ensuring sponsors are meeting their requirements and hold robust evidence to support the claims made on their products.

The majority of the issues outlined in CHF's earlier submission still apply. Overall, CHF is disappointed that the TGA has not maintained the strength and clarity of the evidentiary requirements contained in the original version of the document. ***We also note that none of CHF's recommendations have been addressed in the current version of the document.***

Comments are provided against Version 2 of the draft document.

[1] CHF's earlier submission can be found at https://www.chf.org.au/pdfs/sub/sub-873-evidence-requirements-for-listed-Medicines-May2012.pdf

[2] Australian National Audit Office 2011 *Therapeutic Goods Regulation: Complementary Medicines (Audit Report No. 3 2011-12).* Commonwealth of Australia, Canberra.

[3] Therapeutic Goods Administration 2012 Half-Yearly Performance Report, January-June. TGA, Canberra.

Version 2 of the draft document

In CHF's view, the original version of the draft document appeared to be targeted at addressing consumer needs, while Version 2 appears to be aimed at reducing the 'burden' on industry. CHF finds this shift disappointing.

However, there are aspects of Version 2 of the draft document that are encouraging. There is a significant amount of detail to support sponsors in their application to List a medicine in both Parts A and B of the document.

Part A outlines the evidence requirements. CHF argues that the omission of the requirement for an 'expert report' severely reduces the strength of the document. This omission is discussed in more detail below. However, this section provides useful detailed information to assist sponsors in their application to List a medicine. As well as going into some detail about what level of evidence is expected from sponsors in supporting indications, including for both scientific and traditional indications, it also provides criteria for sponsors to assess the quality of evidence they hold and plan to use.

Part B provides significant detail about the use of Sources of Established Evidence (SEE) and Evidence Reports, including providing guidance about literature searches and assessment of the level, relevance, quality, outcomes and overall balance of available evidence. The information in this section will be useful for sponsors in clarifying which evidence can be used to support indications.

Recommendation

1. CHF recommends that the level of detail provided in Part A and B of Version 2 of the draft document be maintained to ensure that sponsors are aware of requirements around the quality of evidence and how evidence can be used to support an application.

Expert Evidence

CHF is disappointed at the TGA's decision to remove Section 2 of the original version of the draft document which, among other things, required an 'expert report', to be completed by an independent scientific expert with clearly outlined minimum qualifications, be provided by sponsors as part of their application to list a medicine. This requirement would have ensured that the evidence used by sponsors to list a medicine is objective and reliable.

Instead, Version 2 of the document requires that sponsors hold evidence to support the indications through either completing a 'Sources of Established Evidence (SEE) Assessment Template', or through providing an 'Evidence Report' based on a review and assessment of available literature, in their application to list a medicine. Both processes are conducted 'in house' by the sponsor and, in CHF's view, are inadequate in terms of providing an objective assessment of the evidence. One rationale provided by the TGA for sponsors to provide an 'expert report', as outlined in the original version of the document, was to

> *ensure that the relevant body of evidence is comprehensively and objectively assessed…by an expert with sufficient clinical and critical appraisal skills.*

This assurance is not provided by the proposed arrangements in Version 2.

CHF seeks advice from the TGA on how the proposed arrangements significantly differ from what is required of sponsors currently, and whether they will provide any additional assurance to consumers of the reliability of the evidence used to support indications and claims by sponsors.

Recommendation

2. CHF recommends that the TGA reinstate the requirement for an expert report to be prepared by sponsors to support their application to list a medicine.

Compliance

CHF's previous submission included statistics that showed the high rate of non-compliance by sponsors of Listed medicines. In that submission, CHF noted that the clarity of the proposed evidence requirements in the previous version of the document may go some way to ensuring AUST L products listed on the Australian Register of Therapeutic Goods (ARTG) are compliant with evidence requirements before listing.

Version 2 of the draft document states that post-market regulatory activities will help maintain consumer confidence in the quality, safety and effectiveness of medicines. However, given the current high level of non-compliance by sponsors found by the TGA during its post-market monitoring activities, CHF argues strongly that more rigorous pre-market assessments and regulatory activities are required. The current high level of non-compliance found through post-market activities is unlikely to boost consumer confidence in the quality, safety and effectiveness of medicines.

Further, CHF questions whether post-market monitoring activities provide a significant deterrent for non-compliance with evidence requirements, given that the TGA is constrained in the sanctions and penalties that it can impose upon sponsors.

The changes proposed in Version 2 ('SEE Template' and 'Evidence Report') appear to be predicated on the assumption that poor regulatory adherence is due to sponsor uncertainty about the evidentiary requirements to list a medicine. However, while this may be the case for some sponsors, and in those cases enhancing clarity around requirements may be of benefit, CHF is concerned that others are actively disregarding regulations in order to list a medicine.

Recommendation

3. CHF recommends that the TGA increase post-market monitoring activity in the period immediately following implementation of the new evidence requirements, in order to monitor how well sponsors are adhering to the new requirements.

Public Awareness

CHF reiterates our argument from our submission to the TGA's consultation on the original version of the draft document that the lack of public awareness of the different levels of assessment involved in listing AUST R or AUST L products on the ARTG should be addressed by the TGA.

As we have previously argued, the lack of public awareness of the different levels of assessment involved in listing AUST R or AUST L products on the ARTG, and of the evidentiary requirements for Listed medicines, are areas of concern for consumers. The presence of an

AUST L number on the label of a medicine is often incorrectly interpreted to mean that the product has been reviewed by the TGA for safety, quality and effectiveness. This concern was raised in a number of submissions to the TGA Transparency Review, including CHF's submission.[4]

CHF notes that the TGA has published the *TGA Regulatory Framework* in May 2012, as part of its response to recommendation 6 of the *TGA Transparency Review*. If the public's understanding of the regulatory processes and evidentiary requirements related to Listed medicines is to be improved, it is important that the TGA continue its work it to enhance transparency about its activities. Further, in conjunction with this work, the TGA should also raise public awareness of the reforms and changes it is making to therapeutic goods regulation, including the changes to evidence requirements resulting from this consultation.

Recommendation

4. CHF recommends that the publication of revised evidence requirements is accompanied by activities to raise public awareness of the different requirements for Listed and Registered medicines.

Conclusion

CHF welcomes the opportunity to provide comments on Version 2 of the draft *Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants).*

CHF has significant concerns about the removal of the requirement for an expert report on the evidence for a product to be provided by sponsors in their application to list a medicine. It is CHF's view that the revised requirements do not provide sufficient assurance for consumers that the relevant body of evidence has been assessed comprehensively and objectively prior to listing.

CHF looks forward to the release of the next version of the evidence requirements. We hope that these will retain the level of detail contained in Version 2, while also restoring the strength and clarity in the previous version of the requirements. Given the high level of non-compliance with evidence requirements found in post-market activities in this area, it is critical that pre-market requirements are strengthened in order to protect consumers' interests.

[4] CHF's submission to the TGA Transparency Review can be found at https://www.chf.org.au/pdfs/sub/sub-701-tga-transparency-review.pdf

Consumers Health Forum of Australia

The Consumers Health Forum of Australia (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.

CHF does this by:

1. advocating for appropriate and equitable healthcare
2. undertaking consumer-based research and developing a strong consumer knowledge base
3. identifying key issues in safety and quality of health services for consumers
4. raising the health literacy of consumers, health professionals and stakeholders
5. providing a strong national voice for health consumers and supporting consumer participation in health policy and program decision making

CHF values:

- our members' knowledge, experience and involvement
- development of an integrated healthcare system that values the consumer experience
- prevention and early intervention
- collaborative integrated healthcare
- working in partnership

CHF member organisations reach thousands of Australian health consumers across a wide range of health interests and health system experiences. CHF policy is developed through consultation with members, ensuring that CHF maintains a broad, representative, health consumer perspective.

CHF is committed to being an active advocate in the ongoing development of Australian health policy and practice.

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