Consultation submission cover sheet

This form accompanies a submission on:

The document 'Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants)'	
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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.
Complementary medicine reforms will increase the burden on manufacturers - especially those that are compliant. Their costs will increase to produce medicines that are on the whole deemed low risk. The trickle-down effect of these additional TGA requirements in effect will remove some perfectly compliant but smaller suppliers from the marketplace. Naturopaths need variety in options from suppliers. Monopolies are problematic in any industry. If only the larger companies can afford to comply with the TGA requirements a monopoly in our profession is being sanctioned. This has to be stopped at all costs. In this preliminary phase of consultation we the ANPA expect this very important point to be taken on board for the protection of smaller very compliant and excellent product producers and manufacturers. New TGA requirements must at the same be introduced in parallel with SIGNIFICANT ENFORCEMENT MEASURES. These must include serious penalties and deterrents that penalise non-compliant operators. Failing to introduce these measures at the same time, the TGA will have conducted an exercise in futility, compliant operators will have additional burdens and non-compliant operators will continue with 'business as usual.' The TGA must take into account that disadvantaging compliant operators with more bureaucracy in a sector where the risk for the medicines is in fact low is ill-conceived.
Whether or not you support the revised Evidence Requirements. If not supported, please provide reasons why.
1. Unnecessary complexity - some of the requirements for a review of scientific evidence are difficult or in fact almost impossible to comply with. The requirement for complex statistical calculations and inclusion of power calculations seems inappropriate for listed products that have low-risk ingredients and indications. Listed products are not pharmaceutical medicines and should be treated and regarded differently. The requirement for mathematical calculations to ascertain the clinical significance of every relevant study, even when this has not been reported in the research paper is unreasonable and excessive for this low risk area of health products. What the TGA is proposing for these low risk listed products seems to be overkill in terms of levels of evidence. The guideline itself states that clinical significance is difficult to define. It then goes on to require a clear definition. This is nonsensical and needs to be removed. The template demands the addition of a clinical significance d-value which in itself is only theoretical and rarely expressed in study reports. Importantly, a sponsor or manufacturer who does choose to calculate the power or d-values from a study could be considered as altering the data. This matter has to be very carefully reviewed for what is relevant and in context for CAM low risk products. The requirement to prepare a systematic review for every indication for every ingredient is onerous and excessive. This has to be reviewed and again revised to reflect the real requirement for an industry producing low risk products. 2. Sources of established evidence - there needs to provision to add additional references to the list of resources. 3. Nutrient dose - Part B, section 2.3 - percentages required are higher than the amounts originally prescribed in the TGA Advertising Code.

4. Extracts - there is confusion in the section where it states that in order for an sources of established evidence to support an indication for an ingredient, the method of preparation of the ingredient must be COMPRABLE OR IDENTICAL. The same section also states that an ingredient which is an extract must be produced with THE SAME CONDITIONS, solvents, ratios as referenced. This has to be corrected to the former.

Any additional information on issues not asked in the above questions.

Excessive bureaucratic requirements are concerning and may put small operators out of business. The CAM industry is highly competitive with new products reaching market frequently. These questions and focus in the documentation seems to be entirely focused on the issues for consumers self-selecting and what manufacturers are providing in terms of evidence.

There seems to be a whole category of practitioners that do not seem to get a mention in this report. Many of these listed products should in fact be sold in the context of a full and proper consultation with a naturopath or other relevantly trained practitioner in that modality. The marketplace is rife with products that clearly are out of the professional context of a consumer.

The ANPA would like to see the issues of 'practitioner only' products addressed more fully.

If your comments relate to specific parts of the document please provide the page number and reference.

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