Consumer Healthcare Products Australia
ABN 55 082 798 952
Suite 1, Level 2
35 Chandos Street
St Leonards NSW 2065
+61 2 9922 5111
PO Box 209, St Leonards NSW 1590

info@chpaustralia.com.au
www.chpaustralia.com au

11 October 2019

Complementary and OTC Medicines Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
complementary.medicines@health.gov.au

Dear Sir/Madam

Consultation: Changes to permissible ingredients - Low-negligible risk

CHP Australia welcomes the opportunity to provide feedback on the proposed changes.

CHP Australia is the leading voice and industry body for manufacturers and distributors of consumer healthcare products, which includes non-prescription medicines. We strive to advance consumer health through responsible Self Care and were previously known as the Australian Self Medication Industry (ASMI).

Our key priorities for the industry include improving health literacy, growing the consumer healthcare products industry and increasing access to medicines where appropriate.

Background and Principles

CHP Australia welcomes the new update process for low-negligible risk changes to the Therapeutic Goods (Permissible Ingredients) Determination ('the Determination'), particularly regarding the provision of consultation and transition arrangements. It is encouraging that consultation regarding this process has yielded a mechanism that allows for business predictability and minimises the cost burden on industry while balancing the needs of the consumer and the obligations of the regulator. Further work is needed to address ongoing challenges with higher risk changes to the Determination and to improve and streamline the processes for very low content excipient ingredients.

Overall, CHP Australia is supportive of the proposed amendments to the Determination, however two main principle-based issues have been identified. Specifically, the presentation of the proposed warnings and the availability of meaningful information for industry regarding Expert reviews of these substances.

Regarding the presentation of the proposed warnings, industry is concerned that the increasing number of warnings and the level of detail included in these warnings is at risk of becoming unmanageable from a labelling perspective. There are also concerns that the amount of information being provided on the label is likely to cause undue distress to consumers e.g. discussion of potential future fertility issues could be distressing to some consumers even

though they are not part of the at-risk population. Consideration should be given to simplifying label statements to minimise this potential distress and to reduce over-crowding of label information that impacts legibility of the label and dilutes important information.

In preparing the response to this consultation and trying to understand the rationale of the various proposals it has become clear that these issues have often been a topic of discussion of the Advisory Committee on Complementary Medicines (ACCM). Unfortunately, information from these discussions that could be quite helpful to industry are not routinely made available in a timely manner or to a sufficient level of detail in the meeting statements to be informative. Publicly released FOIs of recent ACCM meetings that can be found do provide useful information on the nature of consideration and enable industry to better understand why particular outcomes have been recommended. CHP Australia request that the TGA give further consideration to how this information could be routinely provided in a timely and informative way that does not necessitate interested parties to resort to FOIs.

Further to this, it is noted that the ACCM only considers information as presented by the TGA and there is no opportunity for industry submissions or representation on this Committee. There are concerns that this contributes to recommendations for label warnings or transition arrangements that omit the commercial practicalities of making these changes. CHP Australia requests that TGA consider how this process might be expanded/formalised to improve the balance of the discussion and the quality of the recommendations.

Feedback on Proposed Changes

Ingredient name	Proposed changes	Comments
BORAX **BORAX PENTAHYDRATE** **BORIC ACID** **SODIUM PERBORATE**	<u>Additional population controls and additional warnings:</u> When the maximum recommended daily dose of the medicine provides more than 3 mg of boron and the medicine is for internal use and/or oral application, the following warning statement is required on the label: • (BORON12) 'Do not give to a child less than 12 years old as this medicine contains boron and may impair fertility in the future.'.	CHP Australia does not oppose the introduction of additional warning statements and population controls for boron containing products, however the proposed presentation of the warning statements appears excessive, will take up limited label space and are likely to cause undue concern to the average consumer. Boron is commonly used in multivitamin/mineral products that already require substantial information on the label for relatively small containers. Over-crowded labels reduce the legibility, become difficult

	When the maximum recommended daily dose of the medicine provides more than 1 mg of boron but less than 3 mg of boron and the medicine is for internal use and/or oral application, the following warning statement is required on the label: • (BORON2) 'Do not give to a child less than 2 years old as this medicine contains boron and may impair fertility in the future.'. When the medicine is for topical use for dermal application, the following warning statement is required on the label: • (EXTRNL) 'For external use on unbroken skin only.'' (label warning or directions for use).	for consumers to interpret, and risk diluting important information. In this regards, the only information required on the label is "Do not give to a child less than [12]/[2] years old" with respective cut-offs in the validation rules. While the additional information "as this medicine contains boron and may impair fertility in the future" is helpful to sponsors and consumers with a particular interest, this could appear as an explanatory statement within the Permissible Ingredients Determination and potentially on the ARTG record. This level of detail is likely to cause undue distress to the average consumer and should not need to be required on the label. Additionally, adopting the warnings as per European Medicines Agency (EMA)[1] does not take into account the higher risk in the European Union (EU) environment associated with the higher levels of boron permitted under EU regulations (>10mg/day of Boron) that the warnings are attempting to mitigate. Current dosage restrictions enforced by the TGA limit potential Boron exposure to less than 6mg/day for adults, therefore the EMA warnings are excessive in the Australian context.

[1] European Medicines Agency (2017) Questions and answers on boric acid and borates used as excipients in medicinal products for human use. EMA/CHMP/619104/2013

WITHANIA SOMNIFERA	<u>Additional warning statement on the label:</u> • 'Consult a health care professional prior to use if you are pregnant or breastfeeding.'	Add: 'or words to that effect'
VITEX AGNUS-CASTUS	<u>Additional warning statement on the label:</u> • (VAC) 'Vitex agnus-castus can affect hormones in the body and may interact with prescription medicines such as oral contraceptives. Consult your health care professional before use.'	Add: 'or words to that effect'
4-(4-HYDROXY-4-METHYLPENTYL)-3-CYCLOHEXENE CARBOXALDEHYDE	<u>Ingredient to be deleted from the determination:</u> Not suitable as an ingredient for use in listed medicines. New products which contain HICC will not be available for listing in the Register. Sponsors of existing listed medicines will have until the end of the transition period to remove the ingredient from their medicines.	No comments
ISPAGHULA HUSK DRY **ISPAGHULA HUSK POWDER** **PLANTAGO AFRA** **PLANTAGO ARENARIA** **PLANTAGO ASIATICA**	<u>Change of wording for the warning relevant to target population:</u> When a dose for children is stated, the medicine requires the following warning statement on the medicine label: • (PSYLL) 'Should only be used for children on medical advice' (or words to that effect).	The proposed restriction captures product areas that don't present the same need for medical advice when used in children, therefore the proposed restriction will have unintended impacts in its current form. The restriction should be amended so that it only captures the intended usage/product type.

PLANTAGO LANCEOLATA **PLANTAGO MAJOR** **PLANTAGO OVATA** **PLANTAGO SEED DRY** **PSYLLIUM HUSK DRY** **PSYLLIUM HUSK POWDER** **PSYLLIUM SEED DRY**	Clarify wording of the warning statement. Alignment with Required Advisory Statements for Medicine Labels No. 5 for psyllium.	For further information on usage for Plantago spp. ee EMA Monograph[2]. This warning should only be in relation to products indicated as a fibre supplement/bulk forming laxative action or limited to the plant part as 'husk'.
CYMBOPOGON FLEXUOSUS **CYMBOPOGON MARTINI** **CYMBOPOGON NARDUS** **CYMBOPOGON SCHOENANTHUS**	Addition of details on mandatory component: Aldehydes calculated as citral is a mandatory component of Cymbopogon [spp]. The concentration of Aldehydes calculated as citral in the medicine must be no more than 5% for topical use. Alignment with the Poisons Standard June 2019	The Poisons Standard and content restrictions only apply to products for external use and not to internal use. The introduction of the mandatory component as presented will introduce testing expenses for manufacturers as this will become a mandatory component for all products regardless of risk. These requirements should therefore be restricted to Cymbopogon spp when the route of administration is topical.
MALUS PUMILA	Ingredient to be removed from the Determination: Synonym for MALUS DOMESTICA. Sponsors may request TGA to amend existing listed medicines within the transition period.	The summary available in the ingredient database should be updated to reflect Malus pumila as an accepted synonym for Malus domestica – this information is not included in the Determination, so this change is purely administrative.

[2] European Medicines Agency (2014) Community herbal monograph on Plantago lanceolata L., folium. EMA/HMPC/437858/2010 Corr.

Clarification of transition arrangements

While the provision of transition arrangements is definitely welcomed by industry, there is uncertainty about the expectations for transition and when transition dates apply. TGA expectations regarding timepoints and actions for what is included for products on the ARTG (i.e. will TGA cancel Listings that don't have updated information on the day transition ends) or if there are TGA expectations regarding products already released for supply have not been communicated to industry. Implementation of changes in the Determination could include any/all of the following:

- Update of the ARTG
- Cancellation of non-compliant records
- Cessation/commencement of supply of old/new stock/label
- Management of product already in market (i.e. retail, wholesale) and whether any action is necessary

CHP request that TGA provide greater clarity on these expectations so that industry can confidently meet their obligations.

CHP Australia is available for any further information requests or consultation on these matters.

Kind Regards

[redacted]

[redacted]