



## *SFI Australasia's Response to Consultation: Reforms to the Regulatory Framework for Complementary Medicines – Assessment Pathways (February 2017)*

► 20 March 2017  
Prepared by Tobey-Ann Pinder



## SFI Australasia's Response to

### *Consultation: Reforms to the Regulatory Framework for Complementary Medicines – Assessment Pathways (February 2017)*

**SFI Australasia** (formerly **Flordis Pty Ltd**) takes this opportunity to provide comment on the “Consultation: Reforms to the regulatory framework for complementary medicines – Assessment Pathways” released on 14<sup>th</sup> February 2017.

#### **About SFI Australasia**

SFI Australasia (formerly Flordis Pty Ltd) has been an official TGA sponsor since 1999. SFI Australasia's parent company is Soho Flordis International Pty Ltd (SFI), a global company that supplies complementary medicines (CMs) in Australia and internationally.

SFI stands proudly as the parent to three key global brands: Flordis, Klaire Labs and Potter's. SFI and its family of brands has a rich history of delivering CMs globally for over 200 years.

The SFI family of brands represent a commitment to research, sourcing quality ingredients and rigorous processes, delivering premium natural solutions that are renowned for their quality, credibility and reliability by healthcare professionals and consumers around the world.

#### **About Flordis**

In Australia, the Flordis brand is the current recognised and distributed brand of the SFI family of brands. The focus of the Flordis brand is the provision of a wide range of natural medicines with specifically clinically proven benefits. Leading clinicians, natural medicine experts and researchers are part of the extended Flordis and SFI team, and SFI is committed to the further development of the clinical evidence for its products.

A cornerstone of Flordis' philosophy is the “seed to patient” concept of quality where the manufacture of herbal products is controlled from the time of seeding right through to the actual product taken by the consumer. This means our suppliers use standardised controls for cultivation, harvesting, processing, extraction and finished product manufacturing to ensure the products tested in the clinical trials and those used by the consumer are consistently the same.

Flordis products have traditionally been supplied through healthcare practitioners to ensure the correct and effective use by the consumer. Whilst now distributed more widely through the addition of pharmacy distribution, SFI Australasia continues to safeguard the appropriate and effective use of its Flordis products by the consumer through our close partnership with pharmacists and medical practitioners, including medical specialists.

We believe that we have a specific and unique understanding of the regulatory issues, processes and needs relating to complementary and natural medicines in Australia, particularly with our **experience with Listed and Registered CMs**. Before a recent change in sponsorship, the then Flordis product IBEROGAST (a combination of 9 herbal ingredients) became the first **registered** complementary medicine of its type, supported by more than 19 clinical studies.

As such we have attentively provided our commentary in submissions, and subsequent stakeholder engagement sessions, throughout the Expert Review of Medicines and Medical Devices Regulation (the MMDR Review) process. We sincerely welcome further engagement in the government implementation plans of the Recommendations and reforms.

## Our submission

We welcome the commitment of the Australian government to review regulatory process and implement regulatory reforms to improve the management of public health risks and protect the public interest in relation to the regulation of CMs.

A functional and transparent regulatory framework for CMs is pivotal to increase consumer confidence in the Complementary Medicines industry, and thus, we fully support the objectives of the MMDR Review and the TGA's objectives in their proposed regulatory reform implementation.

Given that the regulation of CMs in Australia has drawn criticism from both consumers and industry, we support the need to find the appropriate balance between improving the safety and efficacy of CMs whilst encouraging a viable and robust industry. We believe these two competing interests can converge whereby a viable and sustainable industry is promoted by being one where products are safe, reliable, consistent and efficacious.

We look forward to the outcomes of a regulatory reform on CMs to represent a clear and consistent regulatory framework with a fair representation and differentiation of the evidence behind products.

We sincerely appreciate your consideration of our submission.

## 1. Purpose and Scope

**SFI Australasia response:** We support the objectives of the MMDR Review, and the related principles guiding the TGA's proposed reforms.

## 2. Background

**SFI Australasia response:** We look forward to the outcomes of the regulatory reform to be one that is a clear and consistent regulatory framework with a fair representation of the risk associated with CMs, and importantly, one that recognises and differentiates the varying levels of evidence supporting efficacy of CM products.

Overall, we support the objectives and introduction of a **new pathway** that adequately assesses (premarket) the evidence behind certain CMs allowing for them to communicate efficacy to the consumer which will assist consumers in making more informed healthcare decisions. Critical to this implementation, and to ensure it is ultimately meaningful in its operation, is the differentiation between this new pathway and Listed medicines, and the education of the consumer.

### 3. Assessment Pathways for complementary medicines

#### A risk-based hierarchy for therapeutic indications

- 3.1. Do you agree with the proposed indication hierarchy and the criteria proposed to distinguish the three medicine pathways?
- 3.2. Do you envisage any difficulties with the criteria used to include or exclude products from the new pathway?
- 3.3. What other considerations may need to be taken into account in implementing the new pathway?

**SFI Australasia response:** We agree that a risk-based hierarchy is appropriate to distinguish the three medicine pathways for CMs. Fundamentally, we agree with the criteria proposed and strongly support the introduction of a **new pathway** that adequately assesses (premarket) the evidence behind certain CMs allowing for them to communicate efficacy to the consumer that is in line with their scientific evidence. This will assist consumers in making more informed healthcare decisions, and help consumers be better equipped to differentiate the evidence behind CMs and their claims. It is a welcome reform given the current vast variation in levels of evidence that exists to substantiate CMs.

We generally support the criteria proposed to be used to distinguish the three medicine pathways. However, in regards to the indications criteria, we would like to raise the question why the new pathway cannot also make high level indications if there is specific evidence to support the claims and the public interest criteria are met. It is proposed later in the consultation document that the new pathway will be assessed for efficacy data “at a similar standard that applies to registered complementary medicines”. Therefore, why would the indications eligible to be included in the new pathway not be able to be in line with the efficacy data assessed and include higher level indications if supported to the same level of efficacy as a registered complementary medicine?

Further, registered complementary medicines are still available for self-selection and thus there is no difference in the availability and intervention of a healthcare professional to propose a different risk in communicating the efficacy to the consumer. We ultimately agree that a risk-based hierarchy is necessary, including where appropriate healthcare professional intervention, but the principles in the public interest should be applied equally across the pathways of CMs to determine suitability of the pathway.

If based on appropriate levels of efficacy and evidence (as is discussed in a later section of the consultation), we do not envisage any difficulties with criteria used to include or exclude products from the new pathway. However, to ensure it is ultimately meaningful in its operation, there needs to be education of the consumer, and healthcare professionals, in regards to clearly defined differences in the level of evidence between Listed medicines and the new pathway.

We support that indications for entry into the new pathway should not be merely ‘standard’ permitted indications, and that products supported by solely evidence of traditional use are not appropriate for the new pathway (without additional scientific evidence supporting the indications). We further support that there should not be ‘provisional’ approval in the new pathway (i.e. pending outcomes of clinical trials). It is appropriate that the application is assessed on the merit of the scientific data available at the time of application.

We do support the ability to apply for an extension of indications upon the availability of new scientific evidence, such as an outcome of a clinical trial. This process needs to be further defined and clarified for the new pathway (including fees, timelines, guidelines for submission, etc) as it has not yet been clearly delineated.

Other considerations that may need to be taken into account in implementing the new pathway that are not fully addressed in the rest of the consultation include: actual cost of evaluations, actual timelines of evaluation, some transition complexities for current Listed medicines applying for the new pathway, the alignment with TGO 92 and feasibility of proposed transition timelines, details of the proposed education program for the public, and the development of evidence and submission guidelines for the new pathway.

Also, a final proposal of how this new pathway will be referred to in name and on packaging is still eagerly anticipated for consultation.

### Approaches to establishing efficacy

3.4. Do you agree with the proposed methods to establish efficacy for products included via the new pathway?

3.5. Is the proposed approach to establish efficacy for current listed products that have a restricted representation exemption appropriate?

**SFI Australasia response:** We agree with the proposed methods to establish efficacy for products included via the new pathway. Importantly, we support that efficacy data on finished product should be required for products to be eligible to be included on the ARTG via the new pathway.

We strongly support that Method 2 (a data package consisting of efficacy data for ingredients, formulation, and justification) should **only** be able to be utilised for products that are composed of defined chemical entities such as vitamins, amino acids and minerals, and that herbs, herbal extracts, animal products and probiotics are ineligible for inclusion via Method 2 (and therefore must be eligible for the new pathway by Method 1, by providing clinical data on the finished product that supports the specific indication).

Importantly, the exclusion from Method 2 for herbal medicines recognises inherent problems with relying on ‘generic evidence’ that is not on the actual medicine marketed. Furthermore, it recognises the significant limitations of relying on phytoequivalence to equate efficacy. In herbal medicine, there can be great variance between products, even if they appear to use the same active ingredients, due to the plant (and part) that is used, growing methods, harvesting processes and manufacturing methods (for example). Current technology may allow for evaluation of certain deemed ‘active’ compounds within a herb or herbal extract, but this may be only a snap shot of the

actual activity of the finished product clinically. Therefore, in evaluating applicability of clinical evidence to support an indication for a herbal medicine, the strength and **relevance** of the evidence to the product is integral.

We believe that further clarity and detail is required on the proposed approach to establish efficacy for current Listed medicines that have a restricted represented exemption. For instance, the proposed approach does not adequately address that a restricted representation has already been assessed and approved against the requirements of efficacy and satisfying the public interest criteria. It seems unfair for them to have to undergo assessment again.

Additionally, it is mentioned that the public interest criteria can be met by evidence of efficacy. More thorough guidance and explanation should be provided on restricted representations criteria, including the public interest criteria, and how they can be met by evidence appropriately within the new pathway.

### Evidence requirements

3.6. Are the evidence requirements appropriate for the new pathway?

3.7. Do the proposed levels of assessment align with the proposed risk-based hierarchy?

3.8. What other considerations may need to be taken into account in implementing the new pathway?

**SFI Australasia response:** We strongly support that the minimum standard of efficacy evidence for products assessed via the new pathway be higher than the level required to be held by sponsors to support non-efficacy assessed medicines (and that the permitted indications for non-efficacy assessed medicines reflects this difference from a risk perspective).

We agree that the evidence requirements for the new pathway are appropriate, but only if the proposed methods or approaches to establishing efficacy are mirrored in the evidence requirements. For instance, Method 2 (a data package consisting of efficacy data for ingredients, formulation, and justification) should **only** be able to be utilised for products that are composed of defined chemical entities such as vitamins, amino acids and minerals (i.e. herbs, herbal extracts, animal products and probiotics are ineligible for inclusion via Method 2). This point is not explicitly made in the consultation document with regards to Table 4 (Evidence dossier requirements for the new pathway), which we believe is an oversight.

In particular, we would like to reiterate that evidence required for Category D in Table 2 (Proposed categories of evidence) should be restricted to product specific clinical trials for herbal medicine products to align with this approach. Notably, an intrinsic problem with relying on 'generic' systematic reviews in herbal medicine is that the evidence across a variety of herbal products with a 'type' of ingredient (i.e. species of a herb, e.g. *Hypericum perforatum*) will inevitably be inconclusive, or not representative of effects of a product, because the review considers evidence across varying products that have significant diversity. Therefore, consistency in outcomes cannot be expected in these types of systematic reviews because as the products vary, so too will the

results. Specific evidence should be the primary evidence required to demonstrate efficaciousness and effects of a herbal medicine product (as per Method 1, in Table 4).

A consideration that may need to be taken into account in implementing the new pathway is that the consultation suggests that “additional evidence may be required to support advertising claims to ensure that they are truthful, factual and not misleading”. As is discussed later in our response, there is a lack of clarity about how advertising claims will be assessed for low level Listed medicines, if they are not being included in the permitted indications list (given advertising claims are not necessarily indications). It seems a discrepancy and unfair advantage that advertising claims (and non-compliance of such claims) will not be adequately controlled or assessed in lower level Listed medicines whilst the new pathway will be required to have evidence for such claims assessed (if on the label). There is a risk that non-compliance in Listed medicines will perpetuate based on possibly dubious or unsubstantiated marketing claims that are not considered indications, and this could negatively affect the consumers ability to differentiate between the pathways.

Another consideration that may need to be taken into account in implementing the new pathway is how the evidence requirements should be presented in application. It is mentioned that the Evidence Guidelines for Listed medicines will be updated accordingly but further clarity on the application package and process for the new pathway is necessary for implementation.

## 4. Implementing a list of permitted indications

### Criteria for permitted indications

4.1. Are the proposed criteria for inclusion of an indication on the permitted indications list appropriate?

4.2. What other considerations should be taken into account in implementing the permitted indications list?

**SFI Australasia response:** In general, we agree that the proposed criteria for inclusion of an indication on the permitted indications list should aim to help improve compliance of industry, which will thereby help to improve consumers’ confidence in CMs.

We support that only low level indications are suitable for inclusion in the permitted indications list based on the criteria and risk-based hierarchy for therapeutic indications. We also agree that the use of any higher level indications should require a pre-market assessment approval (including evidence review) through either the new pathway or registration.

Essentially, across all of the proposed pathways for CMs, the reforms should seek to support that medicines are able to effectively communicate to consumers ‘what they do’ in an appropriate and balanced manner that is representative of the level of evidence for particular health outcomes. We support a framework for appropriate levels of indications that supports this aim.

Therefore, a permitted indications list must encompass all possible indications for medicines with a lower risk profile but should still be met with compliance efforts that closely manage and audit the

application of such a list. As such, TGA should be committed to increased compliance efforts for Listed medicines to ensure any ‘new’ system of permitted indications is not tarnished by those medicines that use particular permitted indications without sufficient levels of evidence, which would perpetuate the reputational loss to the CM industry as currently experienced.

One concern for consideration is the mention that ‘[c]ertain indications of listed medicines that are currently available for supply may not meet the criteria...’, and an example is given of biomarker indications that relate to a disease that is potentially serious and may result in a consumer delaying appropriate medical treatment. This understanding may imply that the use of biomarker indications that are in line with the evidence to support effects on such biomarker in that range may not be able to be adequately conveyed because all biomarkers ultimately may represent a disease or condition.

We support that the way that biomarker indications are considered should align with the level of efficacy on such biomarkers (for instance, if they have a significant effect on a certain range of biomarker that the indication align with such action). Stating qualifiers to reword indications so that they are compliant with the new criteria may not actually provide a solution, as the qualifiers might not actually represent what the scientific evidence supports. For example, if evidence supports the reduction of mildly elevated cholesterol levels to normal range, it is not appropriate to qualify an indication such that it states it helps maintain normal cholesterol levels (as this is not what the evidence actually shows). Thus, we believe that further consultation should be gathered on how to best develop biomarker indications in particular and work through this more complex area of indications.

Another consideration that we have noted in our feedback to the “Consultation: The regulatory framework for advertising therapeutic goods – November 2016”, is that in Recommendation 38 from the MMDR Review, and in the consultation on advertising for therapeutic goods, it is proposed that advertising claims be consistent with permitted or approved indications on the ARTG. However, we would like to reiterate that careful consideration needs to be made in implementation of this understanding, as the ARTG for Listed medicines is only going to include ‘permitted indications’ (as is proposed in this current consultation) and *not* other types of marketing claims. Other marketing claims that can be substantiated *should* be allowed in advertising, otherwise the ability to communicate honestly and effectively to consumers will be stifled. Therefore, we encourage departments within the TGA to work together in their implementation plans for the Recommendations especially where there is overlap in application (such as Recommendation 38 on permitted indications and the advertising of therapeutic goods reforms).

It is proposed that the TGA will also specify certain indications that will not be included in the permitted indications list. We support this endeavour as it should further add clarity for industry, consumers and other stakeholders, however, we believe that if implementation timing is affected in creating a ‘negative’ permitted indication list, then the primary objective should be to create the permitted indication list in first instance. Furthermore, the proposal to only include an indication in the non-permitted indications list following detailed stakeholder consultation is crucial, as a negative determination should only be made after a carefully considered approach.

Overall, we agree that consultation with stakeholders in the development of a comprehensive list of traditional and scientific indications that meet the criteria is essential.

## Implementation of the permitted indications list

4.3. Is Option 2 for selecting indications for inclusion on the ARTG and on product labels and promotional material suitable to address the objectives for permitted indications?

4.4. What other considerations should be taken into account in implementing the permitted indications list?

**SFI Australasia response:** We agree that Option 2: ‘Core permitted indications which can be modified with pre-approved qualifiers’ for selecting indications for inclusion on the ARTG is suitable to address the objectives for permitted indications, but we are also of the opinion that Option 3: ‘Build a unique indication from pre-approved indication components’ is preferable (if feasible for implementation).

Option 3 appears to be more flexible for permutations of indications to reflect the flexibility required to be able to align indications with the evidence held for the medicine.

Option 2 may still create difficulty in aligning evidence to the indication as qualifiers may not adequately capture an appropriate communication of a health outcome measured in the evidence that may not be on the core permitted indications.

For all the options, we believe a further mechanism is required to reign in any continued high levels of non-compliant indications beyond just implementing a reduced flexibility into the new permitted indications list. Users of the ‘new’ system of permitted indications could still inappropriately select indications without sufficient levels of evidence (given there is no premarket efficacy approval in this pathway), perpetuating non-compliant behaviour and a lack of consumer protection (and thus low consumer confidence in the industry is also continued). Therefore, as mentioned previously, we support TGA being committed to increased compliance efforts for Listed medicines to ensure that the application of the ‘new’ system of permitted indications operates appropriately and compliantly, regardless of the Option for mechanism.

We believe that the proposal that the TGA will prepare a legislative instrument comprising a consolidated list of all permitted indications could be limiting. It may slow the ability to utilise the permitted indications list given it would require legislative approval for inclusion or delisting of a permitted indication. An important mechanism to the permitted indications list is the responsiveness to reality, particular in the relationship to appropriateness for the class of medicine. It seems a challenge for practicality if a legislative instrument needs to be updated (even if proposed quarterly), given the current challenges in timeliness that are faced with updating legislative instruments with other regulatory decisions (i.e. new ingredient approvals). A legislative instrument of permitted indications seems to be wrought with limitations in timely implementation and transition, and may ultimately foster a cumbersome and unwieldy mechanism. A return on investment for such an endeavour seems unlikely.

## 5. Claiming evidence of efficacy

## Criteria for use of a claimer

5.1. Do the proposed criteria for the use of a claimer address the objectives for the recommendation?

5.2. What other considerations should be taken into account in implementing this recommendation?

**SFI Australasia response:** We agree with the proposed criteria for the use of the claimer, and that the criteria address the objectives for the recommendation.

In particular, we support that a claimer is appropriate for CMs evaluated by the TGA via the new pathway, and registered CMs that have undergone pre-market evaluation (but not 'grandfathered' registered medicines or Listed medicines given they have not undergone pre-market evidence assessment).

The use of a claimer for CMs that have had their efficacy assessed is an important differentiator not only in the marketplace, but also in educating the consumer on the differences between the pathways of assessment of CMs and their differing levels of evidence requirements. Communicating to the consumer the differing levels of evidence behind CMs is in the public interest and supports the appropriate use of medicines.

We agree that in order to keep with the intent of the MMDR Review's Recommendations for the new pathway, that Listed medicines (that were not assessed as part of the new pathway) that have subsequently undergone post-market evidence assessment through a compliance review should not be able to use a claimer of having efficacy assessed. We support the intent of the Panel in this regard because post-market assessment is simply a policing of the self-declaration submitted at time of Listing to ensure it is true and accurate, and merely audits compliance in line with a sponsor's self-declaration.

It is noted in the criteria that a claimer must comply with advertising requirements. In order to do so, it should be considered that the *Therapeutic Goods Advertising Code 2015* needs amendment such that the use of a claimer is not in breach of provisions such as stating or implying government endorsement.

## Use of a claimer

5.3. Will the use of a claimer on complementary medicines have any unintended consequences?

**SFI Australasia response:** We agree that the use of a claimer on promotional materials, including the product label is appropriate. The positives significantly outweigh any unintended consequences.

It is well known that under the current regulatory system, consumers do not understand the regulation of CMs nor the evidence levels behind CMs. We believe implementation of a clear,

factual and accurate statement (such as a claimer) is a positive move towards increasing consumer education and understanding around what the TGA does in its regulatory authority capacity with regards to CMs. Furthermore, it raises awareness around the differing evidence levels behind medicines, and differentiates this in relation to the different proposed assessment pathways. As such, a claimer should increase consumer understanding and confidence in the CM industry and TGA.

An unintended consequence of the use of a claimer may be that the time to market for a product may be delayed. However, this is probably not directly related to the use of the claimer itself, but instead the assessment pathways. Time to market is delayed with the new proposed pathway (and registered medicines) because artwork printing cannot be confirmed until approval is received for the application. However, the benefit of being able to include a claimer on promotional materials, including the product label, offsets the consequence of needing to have a longer time to market strategy for products.

A consequence that is mentioned by the TGA in its consultation document in this section that is worth reiterating is that legislative changes will be required to allow the use of a claimer. In particular, the *Therapeutic Goods Advertising Code 2015* needs amendment as it currently prohibits sponsors from implying that the TGA or any other foreign government authority has endorsed or approved the efficacy of a product. We support the timely and appropriate legislative changes to be made to facilitate the implementation of the use of a claimer.

## Presentation of claimers

5.4. Should the claimer be presented as a visual identifier as well as a statement?

5.5. Do you have any views on the possible wording or design of the label claimer?

5.6. What other considerations should be taken into account in implementing the claimer?

**SFI Australasia response:** Yes, we strongly support that the claimer should be presented as a visual identifier as well as a statement (Option 2).

The appearance of the claimer needs to be direct and clear to enable consumers to make informed healthcare decisions about their medicines. A visual and statement claimer best achieves this aim.

It also has the benefit of best educating the consumer to enable differentiation of the assessment pathways for CMs. This is important because if the consumer does not understand the differences between the assessment pathways for CMs clearly, the implementation of the new proposed pathway becomes meaningless and pointless. TGA should take the opportunity to be a global regulatory leader in helping to improve the consumers understanding in the regulation of medicines, in particular CMs, which also allows for consumers to ultimately make more informed healthcare decisions.

We support possible wording of a label claimer that accurately and factually represents the situation that the TGA has reviewed and approved the efficacy evidence for the indications of the

product. We are not in favour of wording that it has been ‘independently assessed’ given this does not properly inform the consumer that the TGA has undertaken this process, and could be misconstrued as an industry initiative or other marketing claim. Furthermore, we suggest that the consumer may not understand or comprehend what ‘efficacy’ means and the TGA should consider implementing wording that the consumer can best understand to portray this concept, such as ‘effectiveness’. For example, we would likely support a claimer statement such as “Evidence of effectiveness of the product has been assessed by the TGA”.

For a visual representation of the claimer, we support a visual representation that is clear, identifies the key concepts of approval, TGA and effectiveness. We do not support any numbers to identify pathways, as this can be easily misunderstood as a ranking rather than a pathway identification. Moreover, since the intermediate and registration pathways will have the same or similar levels of clinical evidence evaluated there should be no differentiation of these for the claimer (given the claimer is differentiating and educating the consumer on the assessment of the level of evidence for indications). Therefore, our view is that a visual representation with a ‘tick’, ‘TGA’, and ‘effectiveness’ may be most demonstrative and appropriate to educate and adequately inform the consumer.

Since an approved presentation for the claimer statement will be developed and will be the same for all products (with no variation, e.g. standardised font size, colour, location, and wording of the claimer), a final decision of the presentation should be closely consulted with stakeholders in further consultations (once there are more detailed statement and visual claimer examples developed).

We agree that a consumer education campaign is essential. We look forward to the TGA’s proposal of how they intend to implement a consumer education campaign, and hope it will be wide reaching across multiple forms of media, and locations (including point of sale).

Importantly, an education campaign for healthcare professionals is also vital, as healthcare professionals are often a conduit of learned information about medicines (even if they are medicines that can be self-selected such as CMs) and should be appropriately educated to understand the regulation of medicines in Australia, including CMs.

## 6. Incentives for innovation

### Protection for new ingredients

6.1. Is the proposed process and mechanism to provide market protection for new ingredient applicants appropriate?

6.2. Is the proposed 2 year period of exclusivity an appropriate period to reward the innovation and allow for return on the investment made?

6.3. Should multiple applicants be able to apply for exclusive use of the same new ingredients using their own data during the exclusivity period?

#### 6.4. What other considerations should be taken into account in implementing the proposed incentives for innovation?

**SFI Australasia response:** We strongly support the Panel's account (from the MMDR Review) that encouraging greater development of evidence relating to CMs would have the benefits of greater consumer confidence in the efficacy of CMs, and the improved reputation and competitiveness of the sector.

A general lack of incentive for innovation has repeatedly been touted by industry as a barrier to the development of evidence relating to CMs. Whilst we agree that some incentive to innovation is desirable, we are of the opinion that if a regulatory system can adequately differentiate products that have invested in the development of evidence of their products (including differentiation to the consumer) then further incentives should not necessarily be required.

However, we see the challenge that is faced when a significant investment is made into the application for a new ingredient to be included in the Therapeutic Goods (Permissible Ingredients) Determination, when any sponsor can then use that ingredient in a product on the ARTG through the Listing pathway without having to undertake the same level of investment. As is mentioned in the consultation, there are other mechanisms in intellectual property rights available such as patents, but these are usually only available for things like patents on manufacturing process or claims related to a natural substance, and not for the use of the ingredient itself. Further, it is a significant cost and burden to achieve and uphold patents (i.e. often cost prohibitive from the litigious nature of the defence). Trademarks, or 'proprietary ingredients' serve as a market differentiator if the message can be adequately communicated to the end user (but it is often difficult and not effective).

Therefore, we agree that the proposed process and mechanism to provide market protection for new ingredient applicants is appropriate in this instance. A period of 2 years exclusivity seems an appropriate period to reward the effort and investment made into an application.

Further clarity is required to understand how multiple applicants would be able to apply for exclusive use of the same new ingredients during the exclusivity period using their own data. It should be considered a risk whereby certain groups of companies (with significantly more resources than other companies) would effectively work as a cartel in the control of new substances to be used in CMs in Australia, and this consequence should be avoided.

It also should be considered that the current Therapeutic Goods (Permissible Ingredients) Determination is significantly behind in permissibility of ingredients than many other comparable regulated countries. The market exclusivity for some ingredients that are widely used in other jurisdictions in products that are not yet permissible in Australia may at first act as a catalyst to a race to application for ingredient(s). Again, this would benefit companies that have significant more resources than other companies, not necessarily those that are 'innovating' new ingredients per se. It could also disadvantage companies that have invested in preparing an application for a new permissible ingredient but miss out in timing to another more resourced company (when the 'data' relied upon is not unique or either companies 'own' data).

## Protection for efficacy data

- 6.5. Is the proposed process and mechanism to provide data protection for efficacy data appropriate?
- 6.6. Is the proposed 3 year data protection period for efficacy data appropriate to reward innovation and allow for a return on the investment made? Is it excessive?
- 6.7. Should protection be available for new uses of existing substances and/or be available for information that is not in the public domain?
- 6.8. What other considerations should be taken into account in implementing the proposed incentives for innovation?

**SFI Australasia response:** We strongly support the Panel's account (from the MMDR Review) that encouraging greater development of evidence relating to CMs would have the benefits of greater consumer confidence in the efficacy of CMs, and the improved reputation and competitiveness of the sector.

A general lack of incentive for innovation has repeatedly been touted by industry as a barrier to the development of evidence relating to CMs. Whilst we agree that some incentive to innovation is desirable, we are of the opinion that if a regulatory system can adequately differentiate products that have invested in the development of specific evidence of their products (including differentiation to the consumer) then further incentives should not necessarily be required.

We feel there is a lack of clarity and thorough consideration in the proposed process and mechanisms to provide data protection for efficacy data. There are significant consequences that should be considered in granting data protection for products as a simple solution to incentivise the assessment pathways. As such, we do not support the process and mechanism proposed to be provided for efficacy data, including the proposed 3 year data protection period.

In particular we raise that the regulatory framework for the pathways, **if** correctly developed and implemented, should incentivise the investment into product specific evidence. The ability to enter into the new pathway and communicate product specific evidence, including the TGA's assessment of such evidence, to the consumer should be relied upon to market differentiate and is in line with the public interest in educating the quality use of medicines.

Therefore, we reiterate that we support that specific evidence should be the determining factor to grant entry into the new pathway, in particular for herbal medicines (as has been stated in other sections of our response). Further incentivising this pathway would be redundant as another application for a product entry into the pathway should similarly require their own efficacy data, regardless if during a period of data protection or not.

The incentive will be in the way the consumer understands the pathways, which is reliant upon the ability to communicate evidence to the consumer, including in indications and claims, and the education around the differing levels of evidence. If this incentive can be realised (or actualised) then those that hold specific evidence should want to support the education of the public and consumer by sharing their clinical efficacy and evidence to facilitate their understanding of the

differing levels of evidence behind CMs, rather than wanting data protection of such evidence demonstrating clinical effectiveness.

The risk for innovation will be in the ineffectiveness of implementation of the new pathways and regulatory framework for CMs. For instance, if a product in the new pathway cannot be adequately differentiated in the market from AUST Ls with similar ingredients that may have weaker indications or claims but piggy back on the success or effectiveness of a new pathway product, then there is a barrier to innovation to develop further specific evidence. Thus, we believe this principle of the primacy and importance of specific evidence should be built integrally into all aspects of the regulatory reform for CMs.

## 7. Implementation

### Transition arrangements

7.1. Do you agree with the proposed principles to support transition arrangements?

7.2. What other factors should we consider?

**SFI Australasia response:** We support the TGA applying principles to guide the development of transitional arrangements in a way that allows industry to fairly comply with the new requirements. This recognises that industry has generally been a key supportive stakeholder of the MMDR Review panel and the regulator in developing an appropriate CM regulatory reform.

It is appropriate that the TGA has addressed that the transition period should not overly burden industry. This is especially so given the other changes mandated under other already established requirements and transition periods, such as that in TGO 92 (Standard for labels of non-prescription medicines).

However, there seems to be quite a bit more detail that needs to be consulted and achieved before implementation (e.g. legislative changes, further consultation on permitted indications and claimer, etc), and it should at least be considered that three years may be ambitious. The principles for transition should consider the feasibility of the transition period, and support industry in meeting those transition timelines (i.e. adequate education, training, and guidance). This should be considered in light of the other transition requirements like TGO 92.

Compliance with the new provisions will be dependent on not only industry but also the TGA in facilitating the transition. For instance, the requirement for existing listed products with intermediate or restricted representation indications to transition products to the new assessment pathway (or amend to choose low level indications from the permitted indications list) within the transition period will depend on the approval timelines and administration of the TGA in determining if this is actually feasible.

It is stated that TGA will seek to minimise the regulatory burden on industry by keeping compliance costs to a minimum. An example is given in that the application fee during the first 18 months from commencement of the new legislative package will not be charged for sponsors of existing listed

products needing to update their ARTG entry to select permitted indications. One other consideration should be the case where an existing Listed product needs to apply to select permitted indications whilst they are simultaneously applying and/or awaiting an outcome of assessment through the new pathway. Since timelines for approval are not yet set for the new pathway, consideration should be given to these products for a fair compliance cost and transition period.

As has been mentioned previously, another factor that should be considered in implementation and regulatory amendments for legislative change is required amendments to the *Therapeutic Goods Advertising Code 2015*. This was not listed in the anticipated legislative changes needed in this section of the consultation document and should be considered.

## Administration

### Fees and charges

### Assessment timeframes

**SFI Australasia response:** We understand that full cost recovery aligns with the current practice of the TGA for regulatory process and applications, including the new pathway and permitted indications applications, and understand the governments need for such a practice.

However, the consultation document states that the proposed application and assessment fees for the new pathway “will be less than the registered complementary medicines fees” but it is difficult to know whether the new pathway costs will be reasonable and worthwhile to encourage industry to utilise the new reform. Similarly, the timeframes for the new pathway are proposed to be “significantly reduced compared to registered complementary medicines” but it is unclear what the timeline will likely to be. Currently, as was recognised in the MMDR Review, the regulatory scheme for complementary medicines is inadequate in part because the achievement of an AUST R is often not worth the time for application approval and cost (given there is low commercial value as consumers generally cannot distinguish between an AUST R and AUST L complementary medicine). Therefore, timelines and cost need to be considered to make the regulatory reform practical and meaningful for industry (and thus the consumer) so that the efforts and implementation of this reform are not fruitless.

## In conclusion

SFI Australasia supports the commitment of the Australian government to review the regulatory framework and implement reforms to improve the regulation of therapeutic goods, and in particular CMs. We welcome improvements to the regulation of CMs that will hopefully act as a change agent to betterment of the complementary medicines industry.

We anticipate that a functional and transparent regulatory framework for CMs would be positive for our business by ensuring the market is able to be made up of products that are safe, reliable, consistent and efficacious (and able to communicate differentiation in efficacy levels), thereby imparting and improving consumer confidence in the industry.

Thank you for the opportunity to provide comment on the “Consultation: Reforms to the regulatory framework for complementary medicines – Assessment Pathways (February 2017)”. As an interested and invested stakeholder in the CM industry in Australia, and throughout the MMDR Review process, we sincerely look forward to continuing to participate in TGA’s implementation plans for the agreed upon regulatory reforms.