Swisse

TGA Consultation: Reform of Complementary Medicines

Swisse Wellness

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About Swisse

Established over 40 years ago in Melbourne, Swisse is a leading Australian natural vitamin, herbal and mineral supplement company, and with rapidly growing exports is quickly becoming a global success. Recent expansion into sports nutrition, skincare and functional foods has also been met with promising demand. With a significant and growing market penetration across Australia, the Asia Pacific, China and Europe, we are strong believers in selling locally-manufactured products of the highest quality, safety and efficacy

Executive Summary

Swisse Wellness welcomes the opportunity to be involved in the Therapeutic Goods Administration's (TGA) Consultation on the Reform of the regulations governing Complementary Medicines. We appreciate the extensive and collaborative nature of the entire process, noting that the recommendations which are currently being consulted on carry the in-principle support of industry.

As an industry leader, we reiterate our support for the TGA remaining as the primary regulator of complementary medicines and therapeutic goods. In regards to its robust oversight of medicines and medical devices, the TGA arguably provides consumers the most robust regulatory framework in the world.

It is important to recognise that he regulations under consultation will ensure that Australia's Therapeutic Goods framework is commensurate with the industry's risk profile, the increasing body of evidence supporting complementary medicines, and meticulous approach to compliance exhibited by the significant majority of stakeholders.

Swisse contends that these reforms will rectify the longstanding challenges arising out of a singular regulatory framework for complementary, prescription and over-the-counter medicines; securing appropriate access for consumers and removing futile regulatory requirements.

Given the extensive nature of the review, the final reform package should conform to the intent behind the panel's recommendations and the environment sponsors operate in. Three guiding principles should be referred to in the drafting of the regulations.

1. Increased transparency for consumers, healthcare professionals and other stakeholders in relation to the level of assessment conducted by the TGA on Complementary Medicines seeking entry onto the ARTG

2. That assessment pathways and sponsor-side regulations be commensurate with the risk, intended claim and composition of the product seeking entry onto the ARTG; and,

3. The encouragement of an incentive that supports sponsors who engage in innovation and/or new scientific validation of complementary medicines.

Assessment Pathways

Swisse is supportive of the proposal to introduced a new intermediate pathway for entry onto the Australian Register of Therapeutic Goods. The Australian Register of Therapeutic Goods (ARTG) provides multiple pathways to the register. Those pathways have varying requirements, with the level of regulation reflecting different levels of risk.

Currently, under the ARTG there are currently two entry categories, *Registered* (Aust-R) and *Listed* (Aust-L). Under the Aust-R category, complementary medicines are eligible to register but will be regulated to the risk level for pharmaceutical medicines and substances deemed toxic to human health. This presents an unreasonably high financial barrier to entry for complementary medicines, with little cost-benefit flowing onto sponsors.

The Aust-L pathway to the ARTG allows for the introduction of complementary medicines at faster speed to market, while protecting consumer health and safety, but limits incentives for investment in further science to support higher level claims for products deemed to not be toxic.

In the proposed framework, the third evaluation pathway would be the intermediate category on the ARTG. Products submitted through this channel will need meet an evidence threshold that is superior to the expected level for an ordinary listing, however, more relevant to the risk profile of complementary medicines. In the interest of promoting innovation in the complementary medicines industry, the scope of intermediate indications sought through the new pathway should be flexible and judged on the scientific validation, noting traditional 'evidence' would be prohibited from accessing this new category.

Whilst the pathway would provide an "opt-in" solution for sponsors carrying proposed "new level" scientific evidence, it is important that the pathway not be used to force sponsors to re-submit existing indications through evaluation in the new pathway. Alongside other related provisions (including incentives for innovation), the rationale behind this pathway is to provide sponsors an opportunity to access more specific claims where independently verified scientific evidence has been evaluated. At present, sponsors are required to carry evidence of efficacy for indications on a listed product should the TGA request access to it. This requirement in itself negates calls for already approved indications to be re-evaluated through the new pathway.

Risk-Based Hierarchy for Therapeutic Indications

Given the similarity between the proposed hierarchy for low-level indications with the current *listing* pathway, Swisse supports the proposal in-principle. We are unable to provide further comment on the application of the hierarchy until specific consultation is conducted on a future list of permitted indications.

Low-level indications should be awarded on the basis that the indication is either self-diagnosable, self-manageable and self-limiting. Alongside reference to general health maintenance or general health enhancement, these parameters are agreeable as this is the criteria that is used to decipher currently permitted indications.

Swisse agrees that higher level indications should remain within the current registered complementary medicines assessment framework. Representations (be them higher-level, restricted or prohibited) concerning the treatment, cure and prevention of diseases and illness with potentially toxic therapeutic goods would be prohibited for assessment through the new pathway.

Establishing Efficacy and Advertising of Efficacy

Swisse supports Complementary Medicines Australia's view that products assessed via the new pathway be based on finished product evidence, or justification of evidence to substantiate each substance used in the formulation. Where the efficacy of a prospective product has been evaluated, sponsors would have access to a badge, label or marker to distinguish an evaluated product from a listed or registered one. This would address concerns relating to consumer confusion at point-of-sale.

Swisse notes that the distinguishing factor between the existing listing pathway and proposed intermediate pathway is the pre-evaluation of evidence within the agreed time frame and cost-base; therefore, it is expected that sponsors will maintain the responsibility to self-assess quality and safety of the evaluated product, not dissimilar to the requirements for listing.

Furthermore, where a product has been successfully evaluated for efficacy, approval for use of that claim would also be awarded. This would be provided through a standard claimer, which would be awarded for use on a label where the evaluation has successful been awarded.

Whilst the framework concerning listed products is yet to be consulted on, it is important that calls to introduce a disclaimer on listed products be repudiated, especially given that evidence is required to be held for claims made on listed products. There is clearly no evidence to suggest that disclaimers alter consumer behaviour and minimise non-compliance within the market.

Incentives for Innovation

Further significant investment in science and innovation in the complementary medicines sector will only occur where companies have incentive to invest and can make a return from that investment. This is not currently the case.

Combined with the addition of a third pathway to the ARTG, Swisse believes that intellectual property protection for a period of three years would be adequate to support increased investment in scientific validation to support higher level claims.

Intellectual property protection should not prevent other market participants from conducting their own peer reviewed and published science that may give rise to the same marketing claim inside the three-year intellectual property protection period. Where a company wants to conduct their own science underpinning claim, leading to the use of similar claims, it should be encouraged on the basis that it will ultimately benefit consumers with increased investment in good, publicly available peer reviewed science.