



Response into Review of Pharmacy Remuneration and Regulation Interim Report

Swisse Wellness
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EXECUTIVE SUMMARY

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Swisse Wellness appreciates the opportunity to respond to the Interim Report of the Review of Pharmacy Remuneration and Regulation. This submission relates to the discussion of Complementary Medicines in Section 3.3 of the Interim Report, and follows our original submission into the Review's initial consultation stage.

Swisse commends community pharmacy for the integral role they play in the health system. Pharmacists are trusted members of the community that carry the appropriate training and expertise to advise health consumers and patients of the potential contra-indications, benefits and consequences of using various therapeutic goods.

By providing counsel on the usage of Complementary Medicines, community pharmacists are not deterring consumers from seeking professional medical support. Multiple stakeholders and the panel themselves have conceded that pharmacists have an increasingly important role to play in the health system by promoting health and wellbeing. Imposing regulations on how and where Complementary Medicines can be sold in-store undercuts this responsibility and would do little to prevent consumers from selecting scientifically unverified therapeutic goods.

The panel's commitment to maintaining and promoting self choice of complementary medicines (and other verified Therapeutic Goods) available in pharmacies is appropriate given the major demographic shift towards great individual involvement in actively managing personal health needs and choices.

Consumers expect that pharmacies stock therapeutic goods that are compliant to the relevant TGA regulatory guidelines, and can make traditional use or higher level restricted representations if scientifically validated and supported by credible standards based evidence. As a responsible industry leader, we continue to make a significant investment in improving the evidence base supporting Complementary Medicines.

Pharmacy is clearly the preferred outlet for purchasers and consumers of vitamins and supplements. With approximately 80% of industry's aggregate sales being made through the pharmacy channel, it is clear that consumers appreciate the support pharmacies provide in their selection of complementary medicines.

Summary of Submission

- Swisse Wellness recognises the significant role that community pharmacy plays in the health system, and notes the high-degree of trust for community pharmacists;
- Given the holistic role of community pharmacy in the health system, Swisse welcomes the panel's commitment to not restrict the sale of TGA-approved Complementary Medicines in community pharmacies.
- Swisse Wellness supports the TGA as the primary regulator for quality, safety and (in some cases) efficacy of complementary medicines and therapeutic goods, and notes that consumers are already able to access information on the assessment pathway a given Complementary Medicines has undergone by referring to the label.
- Australian consumers have a strong level of health literacy and are capable of making informed decisions on the suitability of a complementary medicine for their own health.



Background on Therapeutic Goods Administration Approval Process

Swisse Wellness has been a consistent contributor to consultations relating to the reform of regulations governing Complementary Medicines and reforms related to the regulation of pharmacy.

Swisse Wellness supports the TGA 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 and is fundamental to minimising risk from use of therapeutic goods.

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. Typically, Complementary Medicines sold behind the counter carry a restricted representation, and are therefore listed through the 'Aust-R'. Registration through this pathway 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 to 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.

Stocking of Complementary Medicines in Community Pharmacy

It is important to recognise that Complementary Medicines approved for consumption by the TGA are required to have their claims supported by scientific evidence. For listed complementary medicines (Aust-L), sponsors are required to carry evidence supporting the claim, and be prepared to provide it to the TGA if it is requested. Products carrying a restricted representation are assessed for quality, safety and efficacy prior to entry onto market.

Considering the widespread availability of complementary medicines, the expertise provided by the pharmacists secures consumer confidence in the quality, safety and effectiveness of the given product. The industry has invested significant resources with the aim to increase the body of scientific evidence supporting complementary medicines.

The panel's assertion that the availability of Complementary Medicines through the pharmacy channel leads to "unsubstantiated expectations" is highly contestable. It must be made clear that community pharmacists are expected to provide personalised advice on what would be most effective for them, not what is most efficacious according to clinical studies. Given consumers seek complementary medicines and other therapies for improved outcomes, it is important that the discussion about 'health benefits' and 'outcomes' is framed around effectiveness- not efficacy.

Australian consumers generally have a strong level of health literacy and are capable of making informed decisions on the suitability of a given complementary medicine for the prevention of illness or promotion of health and wellbeing. Decisions related to the location of Complementary Medicines within the pharmacy should be informed by the professional expertise of community pharmacists, consumer habits and the assessment pathway that the product has undergone.

Swisse is of the view that whilst pharmacists should be encouraged to provide further detailed advice and counsel on a range of issues, there is no reason to regulate where complementary medicines should be placed in the pharmacy given the low-risk nature of complementary medicines, the robust regulatory framework that governs the sector and high degree of consumer health literacy.

The location of listed Complementary Medicines in front of the counter promotes interaction between consumers and pharmacists, with the few that remain 'behind the counter' likely carrying restricted representations or a slightly elevated level of risk or potential interaction with other therapeutic goods.

In relation to the option to provide specific information on the extent of the TGA's role in approving Complementary Medicines, consumers are able to access such information by referring to the label of a Complementary Medicines. Complementary Medicines that have been successfully listed onto 'Australian Register of Therapeutic Goods' (ARTG) carry an 'AUSTL' number on the label, and those that have been registered on the ARTG similarly carry an 'AUSTR' number. It can be assumed that Complementary Medicines assessed through the imminent third pathway will carry an 'AUSTE' number to signify that they have met a higher evidential threshold. Provided pharmacists continue to highlight this information to consumers, this negates the need to provide separate signage.

Discussions relating to the introduction of mandatory disclaimers on listed Complementary Medicines are ongoing. Swisse has been consistent in our opposition to such disclaimers (in graphical or written form) as all claims are required to be supported by scientific evidence. Additionally, there is clearly no evidence to suggest that disclaimers alter consumer behaviour and minimise non-compliance within the market.

Appendix 1: Notification proving approved Listing on ARTG (AUST-L Number)

