Consultation: Options for the Future Regulation of 'Low Risk' Products
Swisse Wellness

Swisse Wellness welcomes the opportunity to be involved in the Therapeutic Goods Administration's (TGA) Consultation on the future of regulations governing low risk products, and more specifically, 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.

It is worth noting the involvement Swisse Wellness has had with the TGA on previous consultations relating to the reform of Medicines and Medical Devices regulatory framework. As an industry leader, we reiterate our support for the TGA remaining as the primary regulator of complementary medicines and therapeutic goods. The TGA applies appropriate oversight given the risk profile of complementary medicines, whilst providing consumers with the most robust regulatory framework in the world.

Australia's complementary medicines industry has developed global benchmark status due to three key legislative mandates. The first is that products can only be made from permitted ingredients, tested for quality and safety, the second being that any complementary medicine must be manufactured to pharmaceutical-grade good manufacturing practice, and the third is that products must be made in facilities audited to GMP standard by the TGA. Given the effectiveness of this model in mitigating significant public health issues, there is no valid reason to move towards a less accountable framework not administered by the TGA.

At the outset, Swisse wishes to strongly opposes proposals to declare listed vitamins and minerals as not being therapeutic goods (as outlined in Option 3). This includes water soluble vitamins, with any such reform exposing consumers to inadequate regulation that removes world-best practice and lessens regulatory integrity.

Significant investment has been made – and is ongoing – in scientifically validating complementary medicines. The removal of the TGA as the primary regulator of certain vitamins is unacceptable and would expose consumers to increased risk. Current arrangements whereby complementary medicines are regulated by the TGA are the envy of the world- especially given that such action ignores the body of evidence supporting the positive therapeutic effect of such products.

Review of Certain Complementary Medicine Products

Swisse recognises Recommendation 48 of the MMDR; noting that we have consistently stated that public health and safety will only be optimally protected if the TGA administers regulatory oversight of all listed, registered and (upon implementation of third pathway) evaluated complementary medicines. Industry stakeholders, public health professionals and consumers alike have been clear about this, knowing that much of the reason for high therapeutic goods standards in Australia is the regulatory prudence practiced by the TGA.

In relation to water-soluble vitamins, Swisse is strongly of the view that all vitamin and mineral products be treated as therapeutic goods and thus subject to existing requirements for entry-to-market. Complementary Medicines consisting of water-soluble vitamins, notably Vitamin C and B-Complex products, constitute a significant majority of all VMS purchases in the domestic market. With approximately **[x%]** of the population regularly using these products, it is important that confidence in these complementary medicines are upheld by therapeutic grade regulations. These regulations are recognised as being the international gold-standard in therapeutic goods; the removal of these vitamins from thorough TGA oversight could potentially increase the risk of non-compliance within certain parts of the complementary medicines industry.