Pre Budget Submission to Government

Swisse Wellness (Swisse) welcomes the opportunity to make a submission to Government in advance of the 2017-18 Federal Budget. This Submission relates to key Budget measures that we believe will reduce costs in health care and serve to grow the economy.

Our Position

Swisse supports the Government's focus on innovation as a means to support sustained economic growth. The complementary medicines industry can only grow as the result of further investment in science and innovation, supported by an increased opportunity to access to overseas markets.

Building on recent Government reviews of the regulatory framework governing complementary medicines and the Australian Government's success in negotiating bilateral trade agreements in recent years, the 2017-18 Budget is a timely opportunity for the Federal Government to support innovation in the industry through continuing the 'refresh' of the regulatory framework, the elimination of unnecessary regulation and investment in market access support.

An expanding, and innovating complementary medicines industry will see the industry contribute to economic growth at a time where other industries are retracting their contribution of share of Gross Domestic Product. This is particularly the case in the areas of science and R&D and in advanced manufacturing.

An innovative complementary medicines sector will also support an improvement in general population health. In the long term, this may lead to reducing presentations for preventable diseases and therefore lower overall health system costs.

Swisse has four recommendations for this Budget that will support investment in science and innovation from our industry.

- **Recommendation one:** *The introduction of three-year Intellectual Property protection on scientifically supported claims in the complementary medicines sector.*
- **Recommendation two:** *A third category be added to the Australian Register of Therapeutic Goods to allow for the marketing of new complementary medicines with higher level scientific claims.*
- **Recommendation three:** *Allocate responsibility for regulating advertising claims, compliance and complaints of the complementary medicines sector from the Therapeutic Goods Administration (TGA) to the ACCC and Advertising Standards Bureau.*
- **Recommendation four:** *Support early market access and market penetration into international markets for Australia's complementary medicines sector through resourcing embassies with personnel who have specialised industry knowledge in, and a mandate for actualizing the results for the complementary medicines sector.*

About Swisse

Established over 40 years ago in Melbourne, Swisse is Australia's number one 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.

The Economic contribution of the Complementary Medicines Sector

In recent years the complementary medicines sector has matured, with significant growth across all industries relevant to its supply chain, namely agriculture, manufacturing, wholesaling and retail.

Swisse recently commissioned Remplan to undertake independent economic modelling to consider the overall contribution the industry makes to the Australian economy. This research found that the complementary medicines industry contributes annual revenues of $3.18 billion and has a total impact of $8.33 billion on the Australian economy. It directly employs 12,701 people and, including indirect jobs, supports over 28,000 Australians.

There has been significant growth in the sector over the last five years, and this is expected to continue. In Complementary Healthcare Council of Australia's 2011 Annual Report, (now Complementary Medicines Australia), it noted the industry's annual revenues stood at $1.9 billion. Remplan's economic modelling indicates that the industry's gross revenue will continue to increase at 7.3% per annum over the next five years, and that by 2021 the size of the industry will have reached over $4.55 billion.

The growth and economic contribution of the complementary medicines sector is underpinned by increasing consumer confidence in and acceptance of the benefits of complementary medicines and reflects a desire by consumers globally to take control of their own health. It is reflected not just in domestic consumption figures, but also growing exports, particularly to the Asia Region. In 2016 Remplan's research has identified industry exports of over $1.5 billion. In the past 12 months there has been a 36% growth in exports.

Recent Government Reviews

Consideration of sensible regulatory change has already occurred through a number of reviews including the Sansom Review of Medicines and Medical Devices (Chapter 9 related to Regulation of Complementary Medicines), and the Productivity Commission Review of Consumer Law Enforcement and Administration.

We acknowledge the well-informed recommendations that the Sansom Review panel made concerning consumer protection and compliancy arrangements.

Swisse may have further comment to make about the various recommendations of the Sansom and Productivity Commission Reviews. However, this pre-budget submission highlights the most important measures that will support implementation of the reforms and those that we view as most critical to supporting further innovation and investment in the complementary medicines sector.

Rationale for our Recommendations

> ***Recommendation one:*** *The introduction of three-year Intellectual Property protection on scientifically supported claims in the complementary medicines sector.*

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 not currently the case.

Combined with the addition of a third pathway to the ARTG as described in recommendation two, Swisse believes that intellectual property protection for a period of three years would be adequate to support increased investment in science to support advertising claims.

Three-year intellectual property protection for science which supports advertising claims in complementary medicines would represent a small time period of protection compared with

intellectual property protection regimes in other industries such as pharmaceutical medicines or the creative industries. Both of these industries have very substantial time periods of intellectual property protection. This protection has led to increased innovation within the industry and significant growth.

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, peer reviewed science.

Recommendation two: *A third category be added to the Australian Register of Therapeutic Goods*

The Australian Register of Therapeutic Goods (ARTG) provides for multiple pathways to the register. Those pathways have different requirements, with differing levels of regulation to reflect different levels of risk.

The consumer risk profile of the complementary medicines sector should be viewed as more closely aligned to categories under other regulatory arrangements such as 'novel foods' under Food Standard's Australia and New Zealand (FSANZ) or the treatment of 'proven chemicals' under the Australian Pesticides Veterinary Medicines Authority (APVMA).

Under the ARTG there are currently two categories, Registered (Aust R) and Listed (Aust L)

Under the Aust-R category, complementary medicines are eligible to register but will be regulated to a risk level that is appropriate for pharmaceutical medicines and substances deemed toxic to human health. This presents an unreasonably high financial barrier to entry for complementary medicines.

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 claims.

A third category under the ARTG, supported by intellectual property protection as described in recommendation one, would allow for investment in science and innovation, and entry to the register at a cost that is proportionate to the consumer health risk posed by complementary medicines.

The benefits of a further category were recognised by the Sansom Review. Recommendation 39 of the Review recommends the addition of a third option by which sponsors may seek entry to the ARTG. The Commonwealth has accepted this Recommendation, noting that legislative amendments would be required to support it.

Swisse encourages these necessary legislative amendments to be drafted and passed through Parliament as soon as practicable. Any necessary budget allocation to complete this task should be considered in the context of the 2017-18 Budget.

To ensure that investment is channeled into new product lines, or on product lines with new levels of claims, only claims that are supported by new peer reviewed science should be eligible for entry into the new category.

> ***Recommendation three:*** *Allocate responsibility for regulating advertising claims in the complementary medicines sector from the Therapeutic Goods Administration (TGA) to the ACCC and Advertising Standards Bureau.*

There is no longer a need for the TGA to oversee advertising claims when there a mature consumer protection system in place, overseen by the Australian Competition and Consumer Commission and the potential for efficient self-regulatory systems overseen by the Advertising Standards Bureau for advertising claims, compliance and complaints.

The 'novel foods' category of FSANZ carries a potentially similar consumer risk profile to complimentary medicines and yet is not subject to an additional layer of advertising regulation beyond the regulations of the ACCC and the self-regulatory systems overseen by the Advertising Standards Bureau.

The TGA risk-management approach that is appropriate for the public health risks associated with pharmaceuticals is not consistent with the public health risks associated with complementary medicines.

Swisse Wellness remains of the view that the requirement to undergo pre-market advertisement assessment and the existence of a complex, obscure and insufficient complaints resolution process is not best practice. It has had a stifling impact on competition and productivity within the complementary medicines industry.

Swisse was pleased to see the Government accept Recommendation 56 of the Sansom Review, that current mechanisms for managing complaints are disbanded and a new mechanism is established.

While called for by some within the complementary medicines industry, Swisse is not supportive of maintaining an option for voluntary pre-market advertising approval regime as this would add unnecessary cost and complexity to the system, and likely provide unintended consequences of consumer confusion as to the approvals and complaints handling.

The Australian Consumer Law, and regulations administered by the ACCC, should be recognised as the first and foremost set of consumer protection guidelines.

Negligent practice and non-compliance by companies in the complementary medicines sector falls under the 'misleading conduct' provisions of the Australian Consumer Law as outlined in Schedule Two of the Competition and Consumer Act 2010.

The regulatory framework governing therapeutic goods would best serve consumers, manufacturers and businesses if the regulation and appropriate penalties deferred to, or reflected the Australian Consumer Law.

This measure would save on a significant regulatory burden through the elimination of duplicated systems, a burden that is ultimately funded by industry through cost recovery measures. The current system simply detracts from further investment and innovation by industry, and does not provide an independent, transparent process satisfying neither consumers, industry, regulators or Government.

- ***Recommendation four:*** *Support early market access to international markets for Australia's complementary medicines sector through resourcing Embassies with dedicated personnel holding expertise in the complementary medicines sector.*

Building on the Australian Government's recent success with bilateral trade agreements, there is a significant opportunity for further growth in the complementary medicines sector through better market access, particularly in Asia.

Specific personnel with knowledge and expertise in complementary medicines and a mandate to support the industry are necessary in Australian embassies. This will ensure Australia can capitalise on its bilateral trade agreements and the significant growth potential the complementary medicines sector represents, both for itself and also for associated industries in its supply chain. Specifically, the opportunity to source a greater proportion of raw ingredients from Australia's agribusiness sector is exciting and has the potential to have a significant, economy-wide impact.

Industry growth on the basis of existing product categories would allow for further investment by companies in science and innovation and lead to new products that improve consumer health choices and provide further economic growth.

Combined with the other recommendations of this submission, Australia's complementary medicines sector would be well placed to support an Australian innovation culture that will support exports of advanced manufactures, and economic growth into the future.